UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. _____

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DEFENDANTS' PETITION FOR PERMISSION TO APPEAL PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 23(f)

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INTRODUCTION

The district court's sweeping order, certifying both economic-loss and medical-monitoring classes—including 111 hastily grouped consumer and third-party payor ("TPP") subclasses—ignored well-established Third Circuit law in a transparent attempt to exert settlement pressure on defendants. Nowhere does the court explain how any trial involving 428 separate products, made and sold by 28 different defendants, involving claims governed by the laws of 52 separate jurisdictions, could possibly be feasible. Nor does the court differentiate its two multistate medical-monitoring classes from those that this Court has repeatedly rejected, let alone address this Court's skepticism that medical-monitoring classes could *ever* be certified in light of the individualized issues implicated by medical testing protocols. *See Gates v. Rohm & Haas Co.*, 655 F.3d 255, 268 (3d Cir. 2011). Instead, the court elides or downplays individualized issues and massive manageability problems in the name of "promoting Class Action settlement" (D.2261 ("Opinion") 41), effectively taking the position that the rigorous requirements of Rule 23 can (and should) be bent in MDL proceedings.

If allowed to stand, the district court's ruling would eviscerate this Court's prior class action holdings and Rule 23(b)(3)'s predominance and superiority requirements and suggest that MDL judges in this Circuit have carte blanche to ignore the dictates of Rule 23.

QUESTIONS PRESENTED

1. Whether the district court erred in certifying a 47-state medical-monitoring class even though: (a) exposure to the alleged carcinogenic impurities in generic valsartan-containing drugs ("VCDs") varied; (b) there is no scientifically established threshold at which exposure to nitrosamines increases cancer risk; and (c) the relevant state laws are materially different?

2. Whether the district court erred in certifying an "economic loss" class comprising more than 100 subclasses and 52 jurisdictions' laws and implicating individualized facts regarding reliance, causation, materiality and loss?

STATEMENT OF THE CASE

Facts. Between July 2018 and January 2019, several manufacturers voluntarily recalled 428 hypertension medications containing valsartan, due to the presence of trace amounts of N-Nitrosodimethylamine ("NDMA") and/or N-Nitrosodiethylamine ("NDEA"), two nitrosamine impurities. (*E.g.*, D.2012, 1-2.)

The medications at issue were manufactured in different facilities using different processes and varied widely in their impurity levels, but in all cases, any risk of cancer was extremely remote, leading the U.S. Food and Drug Administration ("FDA") to emphasize that patients should continue taking their VCDs until alternatives were available and that the risk of not taking VCDs "greatly outweighs the potential risk of exposure to trace amounts of

nitrosamines." (*Id.* 2.) Nevertheless, lawsuits followed. The Judicial Panel on Multidistrict Litigation transferred many of the lawsuits to the U.S. District Court for the District of New Jersey for coordinated proceedings before Judge Robert B. Kugler in 2019, *see In re Valsartan-Nitrosodimethylamine (NDMA) Contamination Prods. Liab. Litig.*, 363 F.Supp.3d 1378 (J.P.M.L. 2019), after which plaintiffs filed consolidated class action complaints (D.121, D.123).

Plaintiffs' Class-Certification Motions. Briefing on class certification commenced in November 2021. Plaintiffs moved for certification of nationwide and multistate classes asserting claims for: (1) consumer economic loss; (2) TPP economic loss; and (3) medical monitoring.

Consumer Economic Loss. The consumer plaintiffs, individuals who were prescribed and purchased VCDs, claim that the medications were worthless due to the alleged presence of NDMA or NDEA. These plaintiffs proposed a three-phase class trial involving 93 proposed subclasses of individuals. (*E.g.*, D.2008, 2.)

The TPP plaintiffs do not consume prescription drugs and are not at risk of harm from drug impurities. (*E.g.*, D.2010, 1.) Rather, TPPs pay for a portion (or all) of consumer prescription costs under prescription drug insurance plans. (*Id.*) The TPP plaintiffs contend that all TPPs are entitled to full refunds for all VCD payments between 2012 and 2019 because the medications were rendered worthless by the alleged presence of NDMA or NDEA. (*Id.*)

Medical Monitoring. Plaintiffs moved to certify two medical-monitoring classes. The first—a 28-jurisdiction class—sought to assert medical-monitoring causes of action. (D.2012, 2.) The second—a 49-jurisdiction class—sought to recover medical monitoring as a form of relief for nine distinct product liability theories. (*Id.*) Plaintiffs defined both classes to include individuals "who consumed a sufficiently high Lifetime Cumulative Threshold [LCT] of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs manufactured by or for Defendants … since January 1, 2012." (*Id.*)

Decision Below. The MDL court certified nearly all of plaintiffs' proposed classes, including a consumer economic-loss class with 93 subclasses and a TPP class with 18 subclasses. (Opinion 9.) Among its rationales, the court found that this massive nationwide class structure "concentrates litigation efforts for both parties into fewer trials as well as promoting Class Action settlement." (*Id.* 41.)

The District Court's Prior Statements About Settlement. The district court's statement regarding settlement is consistent with its longstanding, expressed desire for a global resolution of the valsartan litigation. In 2019, the court announced its intention to "talk[] to [the parties] early and often about settlement possibilities" (D.77, 3/27/2019 Hr'g Tr. 29:13-30:8), and in early 2022, it imposed on the parties the unusual obligation to retain separate counsel whose role was exclusively to discuss settlement with two appointed special masters (D.1848, 1/5/2022 Hr'g Tr.

20:12-22:20). A short time later, the court told the parties that it intended to instruct the two special masters to "begin aggressively scheduling some sessions" to discuss settlement, in advance of briefing on class certification. (D.1946, 2/28/2022 Hr'g Tr. 43:2-13.)

REASONS FOR GRANTING THE PETITION

This Court applies a "more liberal standard" than other circuits in granting interlocutory review under Rule 23(f). *Laudato v. EQT Corp.*, 23 F.4th 256, 260 (3d Cir. 2022) (citing *Rodriguez v. Nat'l City Bank*, 726 F.3d 372, 376-77 (3d Cir. 2013)). Under that standard, review is appropriate where, inter alia, "the district court's class certification determination was erroneous," "the appeal might facilitate development of the law on class certification," or certification "risks placing inordinate … pressure on defendants to settle." *Id*. Review is justified here under any of these separate grounds.

I. THE CERTIFICATION OF MEDICAL-MONITORING CLASSES WAS ERRONEOUS.

Medical-monitoring classes generally "founder for lack of cohesion" if they are brought under Rule 23(b)(2), or for lack of factual predominance if they are brought under Rule 23(b)(3). *Gates*, 655 F.3d at 264, 270 (affirming denial of certification of medical-monitoring class under Rules 23(b)(2) and 23(b)(3)); *see also Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 143 (3d Cir. 1998) (affirming denial of certification of Rule 23(b)(2) medical-monitoring class). This is so

because an individual's need for monitoring and whether such a need was caused by the defendant's alleged conduct are highly individualized questions that turn on each proposed class member's individual characteristics. Indeed, this Court has questioned whether "the necessity for individuals' medical monitoring regimes can" *ever* "be proven on a class basis." *Gates*, 655 F.3d at 268; *see also Barnes*, 161 F.3d at 146.

If such a case exists, this is not it. The district court ignored overwhelming factual and legal variations that plainly preclude certification under this Court's precedents.

A. The District Court's Order Ignores Factual Variations And Contravenes *Gates* And *Barnes*.

The district court disregarded patently individualized factual questions concerning causation and medical necessity—two issues that this Court has repeatedly held preclude class treatment of medical-monitoring claims.

The medical-monitoring plaintiffs argued that predominance/cohesiveness were satisfied because anyone exposed to nitrosamines in VCDs above the proposed LCTs would have a heightened risk of cancer, justifying monitoring. But plaintiffs pulled the LCTs from thin air; they are not reliably derived through science and rest instead on the unsupported general causation opinions of two experts, neither of whom actually performed an LCT analysis, and one of whom made clear that there is *no bright line threshold* for NDMA or NDEA

carcinogenicity. (D.1750-3, Ex. C, 90.) Moreover, plaintiffs' LCTs vary widely based on class members' different medication dosages, durations of exposure, and the specific VCDs taken. Plaintiffs do not even posit a method to identify which class members satisfy these thresholds, much less to prove on a classwide basis that any heightened risk of cancer experienced by these individuals was the result of exposure to trace amounts of nitrosamines in VCDs as opposed to other factors. Exposure to carcinogens can occur through lifestyle choices (e.g., tobacco use); naturally occurring phenomena (e.g., ultraviolet light); medical treatments (e.g., immunity-suppressing drugs); occupational and household exposures; and even age. (D.2009-16, Ex. 190, ¶ 83.)

Certification was impossible on these facts. As this Court held in *Gates*, a plaintiff must be able to show a single exposure that "would create a significant risk of contracting a serious latent disease for all class members." 655 F.3d at 267; *see also id.* at 268 (class treatment improper where plaintiffs failed to "account[] for the age of the class member being exposed, the length of exposure, [and] other individual factors such as medical history"). Plaintiffs cannot do that here. Even the district court recognized that the "scientific community itself cannot tease out a single, individual cause of cancer from a lifetime of nitrosamine exposure from various sources"; "[n]or can [it] determine the cause of an inflection point making one's likelihood of developing cancer more and more probable." (Opinion 64-65.)

Although the court went on to conclude that "a probable increase in cancer development is attributable to an increase in exposure to nitrosamines—via VCD ingestion, inhalation, etc." (*id.* 65), that simplistic conclusion (even if true)[1] falls miles short of the causation showing that is required to certify a medical-monitoring class. *See Gates*, 655 F.3d at 267; *Barnes*, 161 F.3d at 145 (medical-monitoring class could not be certified because "plaintiffs cannot prove causation by merely showing that smoking cigarettes causes cancer and other diseases" but must also show that "nicotine manipulation caused *each individual plaintiff* to have a significantly increased risk of contracting" disease) (emphasis added).

Individualized questions of medical necessity also precluded certification. As plaintiffs' own expert acknowledged, testing and treatment decisions in a clinical setting are based on the "patient's specific situation," including medical history, comorbidities and the patient's subjective desires. (D.2009-7, Ex. 50, 51:19-52:11.) This is particularly true because some of the screening proposals

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[1] Another MDL court recently excluded plaintiffs' general causation experts' opinions in litigation involving nitrosamine impurities in heartburn medications, explaining, in a detailed ruling that spanned hundreds of pages, that there was no reliable science to support the claim that the impurities posed a risk to users. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, --- F.Supp.3d ----, 2022 WL 17480906 (S.D. Fla. Dec. 6, 2022), *appeal filed*. The district court here, by contrast, denied defendants' *Daubert* motions on general causation in a perfunctory three-page order. (D.1958.) When it was presented with the *Zantac* order in a motion for reconsideration, the district court immediately and summarily denied the motion, without requiring a response from plaintiffs. (D.2210.)

themselves (such as endoscopy and biopsy) pose risks to class member health. (*See* D.2009-25, Ex. 201, 16, 18); *Gates*, 655 F.3d at 269. Although the district court noted in passing that "defendants raise doubts whether a proposed medical monitoring program is medically necessary" (Opinion 65), it never analyzed those concerns or explained how they could be sufficiently overcome to justify certification.[2]

In short, as in *Gates* and *Barnes*, the elements of "causation and medical necessity" "require individual proof," *Gates*, 655 F.3d at 264; *see also Barnes*, 161 F.3d at 145-46, and the district court grossly erred in overlooking those problems and certifying a medical-monitoring class.

B. The District Court Independently Erred In Ignoring Legal Variations.

The court doubled its error by ignoring legal variations within the certified medical-monitoring classes despite widespread judicial recognition that there are fundamental "[d]ifferences in state laws on medical monitoring." *See, e.g.*, *In re St. Jude Med., Inc.*, 425 F.3d 1116, 1122 (8th Cir. 2005) (reversing certification); *In re NHL Players' Concussion Injury Litig.*, 327 F.R.D. 245, 260, 266 (D. Minn.

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[2] The district court also ignored the fact that VCDs manufactured by Mylan and Aurobindo (or by Teva, using Mylan's active pharmaceutical ingredient ("API")) contained only NDEA impurities – not NDMA. Individuals who took those medications were included in the medical-monitoring classes, which would screen for a number of cancers that are only alleged to be linked to NDMA.

2018) (denying certification of proposed multi-state medical-monitoring class under Rule 23(b)(3) because "individualized legal issues will substantially predominate over common legal issues").

The district court thought otherwise, finding that Table 7 accompanying its order "sufficiently accommodates the state law variability" issues raised by defendants. (Opinion 61.) But that table at most purports to divide the relevant states according to whether their laws recognize medical monitoring as an independent claim or a remedy, and whether they require a present physical injury. (*See id.* Table 7.) Even if the district court had properly divided the class along those lines (it did not),[3] it failed to address other fundamental variations, including the necessary showing of injury (i.e., whether subcellular injury suffices), *see Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891, 901-02 (Mass. 2009);

[3] The table erroneously lumps multiple jurisdictions (e.g., Alaska, Idaho and Hawaii) into the independent medical-monitoring class regardless of whether those states have "any court decisions that clearly address the issues related to medical monitoring," *NHL*, 327 F.R.D. at 262, and similarly includes states (e.g., Tennessee) in the remedy class where the law regarding medical monitoring is unclear, *see Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 575 n.7 (6th Cir. 2005) (describing Tennessee law as "murky"). Attached to the Opinion is a confusing appendix that asserts, *inter alia*, that a state without any medical-monitoring law "is just as likely to allow [medical monitoring] as not allow[] it." (Opinion, App. A.) Such an expansion of state law by a federal court violates Third Circuit precedent, too. *See Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 253 (3d Cir. 2010) ("'[W]here two competing yet sensible interpretations' of state law exist, 'we should opt for the interpretation that restricts liability, rather than expands it.'").

whether a treatment for the disease exists, *see Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993); the available detection procedures, *see Petito v. A.H. Robins Co.*, 750 So. 2d 103, 106-07 (Fla. Dist. Ct. App. 2000); whether monitoring is limited to toxic tort cases, *see Sinclair v. Merck & Co.*, 948 A.2d 587, 591, 594-95 (N.J. 2008); or the widely varying state laws that govern the underlying negligence and product-liability claims asserted in the remedy class. (*See* D.2012-2, App. B.)

The district court also offered no plan for properly instructing a lay jury on these varying legal standards. Instead, it announced that any problems with the workability of the proposed medical-monitoring classes could be solved by "th[e] [c]ourt's expertise and experience" overseeing the MDL. (Opinion 66.) That was yet further error; "[t]he rule of law applies in multidistrict litigation … just as it does in any individual case," *In re Nat'l Prescription Opiate Litig.*, 956 F.3d 838, 841 (6th Cir. 2020), including with regard to class certification, *see In re Nat'l Prescription Opiate Litig.*, 976 F.3d 664, 670 (6th Cir. 2020) (reversing certification of negotiation class, which was "designed to fundamentally alter the nature of the MDL—to foster settlement through a novel means of class action"). The fact that cases have been coordinated for pre-trial proceedings under 28 U.S.C. § 1407 does not vitiate the requirements imposed by the Federal Rules of Civil Procedure.

For this reason, too, the district court erred in certifying plaintiffs' medical-monitoring classes.

II. THE DISTRICT COURT'S CERTIFICATION OF ECONOMIC-LOSS CLASSES WAS ERRONEOUS.

The district court also erred in certifying two nationwide economic-loss classes because: (1) individual legal issues arising out of 52 jurisdictions' laws governing five separate causes of action (i.e., 260 legal frameworks) swamp any common legal issues; (2) the court failed to evaluate and credit fact and expert evidence highlighting the individualized nature of issues such as reliance, causation, injury and damages; and (3) there is no practical way to hold a trial involving so many defendants and varying legal regimes.

A. Individualized Legal Issues Predominate.

"[I]n a class action governed by the laws of multiple states … , 'variations in state law may swamp common issues and defeat predominance.'" *Cole v. Gen. Motors Corp.*, 484 F.3d 717, 724 (5th Cir. 2007). Nationwide classes—even those pursuing only one cause of action—are particularly poor candidates for class treatment because legal differences will generally "cast a long shadow over any common issues of fact plaintiffs might establish." *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 946 (6th Cir. 2011) (upholding order striking nationwide class at outset of case).

Nothing about this case makes it an exception to that rule. If anything, it presents even greater complications than the typical nationwide class, spanning 52 jurisdictions, alleging not one but five causes of action, and seeking certification of classes brought by not just one but two types of plaintiffs: consumers and TPPs. Multiplied together, these variations mean that hundreds of legal frameworks could potentially apply to the economic-loss claims at issue in this litigation.

The district court apparently believed that creating a "chart of state law jurisprudence" and splintering the class into 111 subclasses (one of which includes class members from 30 states) would "reduce the overall variability of individualized plaintiffs' legal issues." (Opinion 22, 40.) But the term "'[s]ubclass' is not a magic word that remedies defects of predominance." *Elson v. Black*, 56 F.4th 1002, 1007-08 (5th Cir. 2023). Rather, plaintiffs must demonstrate that "each subclass independently satisfie[s]" Rule 23 and "*how* [the] proposed subclasses would alleviate … obstacles to certification." *Id.*; *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183 (3d Cir. 2014) ("significant burden to demonstrate that grouping is a workable solution").

Even if the groupings adopted by the court accurately reflected the relevant state laws (they do not), there would be 111 legal variations to consider in a single proceeding—more than double the amount deemed unfeasible by other courts. *Pilgrim*, 660 F.3d at 946; *Elson*, 56 F.4th at 1006-07. Moreover, the subclasses do

not address issues of reliance and causation, which vary from one jurisdiction to the next, and therefore cannot overcome Third Circuit precedent precluding certification of multistate classes where the states at issue impose "varying elements of reliance … and causation." *Grandalski*, 767 F.3d at 183; *see Gianino v. Alacer Corp.*, 846 F. Supp. 2d 1096, 1100 (C.D. Cal. 2012) (important distinction between states that "include a reliance requirement in their consumer protection laws" and those that do not). These are just some of the "nuance[s]" of state law, far too numerous to address within the word limits of this petition, that render multistate classes uncertifiable. *Muehlbauer v. Gen. Motors Corp.*, No. 05-2676, 2009 WL 874511, at *5 (N.D. Ill. Mar. 13, 2009).

For this reason alone, certification of the economic-loss classes was improper.

B. Individualized Factual Issues Also Predominate.

Certification was also improper because the economic-loss classes implicate highly individualized factual questions.

First, all of the claims turn on individualized questions related to defect, materiality, reliance, causation, injury and damages. Such variations likewise preclude class treatment.

Reliance, to take one example, makes classwide proof "a near-impossibility" under certain states' laws due to its inherently individualized nature. *Brown v.*

Electrolux Home Prods., Inc., 817 F.3d 1225, 1237 (11th Cir. 2016). Many consumer class members would have taken the VCDs even if they had known of the possible nitrosamine impurities—and therefore could not show reliance (or materiality/causation); indeed, several named plaintiffs (and one of plaintiffs' experts) continued taking their VCDs after the recall. (*See* D.2008, 14 n.79.) That is not surprising since the FDA instructed consumers to "continue taking their medicine until they have a replacement product" (D.2040-1, 10-11) and quantified the risk of injury as perhaps 1 person in 8,000 who took the maximum dose for the maximum period of time (D.2008, 3 n.3; D.2009-12, Ex. 104). Moreover, many TPPs (and consumers) could not show any economic injury because, without the VCDs, they would have had to pay for "alternative hypertension medications," which might have been more expensive. (D.2040-11, ¶ 63.) Determining which TPPs would have paid for which alternative medications requires TPP-by-TPP, if not patient-by-patient, analyses.

Plaintiffs' blanket answer to all of these individualized issues was an expert's opinion that all VCDs containing impurities were economically worthless—even if they worked as intended to lower blood pressure and did not meaningfully raise cancer risk—because there is no "'legitimate' supply curve" for prescription drugs that allegedly contain impurities. (*See* D.2040-1, 9.) This cure-all theory purportedly eliminates individualized issues by positing that all the

VCDs, regardless of dose, efficacy and level of impurity, were worth zero. But this theory is obviously wrong, as defendants' experts explained in their reports and depositions. Indeed, the district court acknowledged defendants' experts' opinions that plaintiffs' theory rested on "sophomoric economics and lack[ed] consideration of drug purchasers' health rationales for continuing to ingest minimally contaminated drugs." (Opinion 22-23.)

Still, despite recognizing that predominance turned on whose experts were right, the district court expressly refused to decide that question. (*Id.* 23.) According to the court, "choosing one theory over the other [would] drive[] a decision as to predominance that bounds too deeply into the province of the factfinder." (*Id.*) That, too, was wrong. This Court has expressly held that "[w]eighing conflicting expert testimony at the certification stage is not only permissible; it may be integral to the rigorous analysis Rule 23 demands." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 323 (3d Cir. 2008).[4] And a district court "may not decline to resolve a genuine legal or factual dispute"

[4] The court also erred in: (1) rejecting defendants' experts' opinions regarding the validity of the proposed medical-monitoring program (Opinion 74-75, 94-95); (2) failing to address the methodological problems with plaintiffs' economist's illogical theory that VCDs are worthless; and (3) excluding/rejecting defendants' experts' opinions that the VCDs did have value, even though the FDA repeatedly advised consumers to continue taking the medications because their benefits far outweighed any theoretical risk posed by nitrosamine impurities, refuting any claim that the medications had no value (*see id.* 77-82, 86-89).

relevant to class certification "because of concern for an overlap with the merits." *Id.* at 324. Ignoring this instruction constitutes "err[or] as a matter of law." *Id.* at 320.

A proper consideration of the experts' opinions would have led the court to deny certification. Other courts that have assessed similar theories have rightly concluded that assigning zero value to a medication that "benefi[ted] many patients" is "not a defensible position." *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68-69 (S.D.N.Y. 2002) (rejecting use of no-value presumption and denying class certification); *see, e.g.*, *Ctr. City Periodontists, P.C. v. Dentsply Int'l, Inc.*, 321 F.R.D. 193, 212 (E.D. Pa. 2017) (predominance lacking because "it is not true that [the dental device] had 'zero value'"). And without judicial acceptance of that theory, a jury would have to evaluate the decision-making processes of millions of individual consumers and hundreds or thousands of TPPs to address issues such as reliance and causation.

The court also suggested that the use of "subclasses" could "account both for the variability in facts and the application of the facts to the required elements of each claim." (Opinion 22.) But the subclasses proposed by plaintiffs and accepted by the court were intended to "account for state law variations," not factual variations. (D.1748, 80; *see id.* 95.) There is obviously no reason to believe consumers from a group of states with similar legal regimes would all have similar

purchasing histories, decision-making inclinations or medical histories. *See Farrar & Farrar Dairy, Inc. v. Miller-St. Nazianz, Inc.*, 254 F.R.D. 68, 75-76 (E.D.N.C. 2008) ("[R]egardless of whether … plaintiffs' proposed subclassing can solve the … predominance problem arising from differing state laws … , it cannot address the predominance problem arising from … individualized factual inquiries").

Second, although the court repeatedly stated that a common course of conduct by defendants "grounds all of plaintiffs' claims," that is not true either. (Opinion 21; *see id.* 37 (defendants' conduct "girds the entire litigation").) As noted above, this case involves 428 distinct VCDs synthesized by different manufacturers of API, who used different chemical processes that are alleged to have created different amounts of NDMA and/or NDEA in different ways. (*See generally* D.1748, 8-38 (explaining different manufacturing processes as alleged by plaintiffs).) A jury could easily find one manufacturer's process to be defective or negligent and another's to be proper. Compounding the issue, plaintiffs have sued several different finished-dose manufacturers that incorporated valsartan with impurities into consumer-ready drugs. Each used different suppliers and took different steps to ensure purity, raising additional defendant-specific issues. (*See id.*) Courts have rejected far simpler class actions, recognizing that no jury could parse so many factual variations. *See, e.g.*, *In re Bridgestone/Firestone, Inc*, 288

F.3d 1012, 1019 (7th Cir. 2002) (granting 23(f) review and reversing class certification in part because case involved "67 specifications" of tires); *In re Ford Motor Co. Vehicle Paint Litig.*, 182 F.R.D. 214, 220 (E.D. La. 1998) (denying class certification in case involving "different models of vehicles, made of different materials, painted … at different plants, using different paint formulae"); *City of St. Petersburg v. Total Containment, Inc.*, 265 F.R.D. 630, 636 (S.D. Fla. 2010) (predominance requirement was not satisfied where claims involved "different models … manufactured by different companies at different times and at different locations"). The comparative maze of facts here should have weighed even more strongly against class treatment.[5]

In short, the certified economic-loss class spans every single state and pits millions of consumers and thousands of insurers against numerous manufacturers of different products, at different strengths and with different impurity levels. Common issues do not come close to predominating, and the district court erred in holding otherwise.

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[5] Because plaintiffs have sued multiple defendants over different products with different alleged nitrosamine impurities, even commonality is not met. The district court's contrary conclusion that plaintiffs satisfied this requirement by alleging that "defendants' conduct of contaminating the VCDs … caused plaintiffs' economic loss" (Opinion 15) fails to grapple with these variations.

C. A Class Action Is A Vastly Inferior Mechanism For Resolving The Dispute.

All of the problems outlined above would combine to create a nightmare of a trial, a reality that the district court's order meets with a rhetorical shrug that strongly suggests the certification order was meant to exert settlement pressure rather than to set the stage for an actual trial, as the trial court effectively admitted by explicitly invoking the prospect of settlement in its ruling. (Opinion 41.)

Rule 23(b)(3)'s "manageability" requirement "encompasses 'the whole range of practical problems that may render the class action format inappropriate for a particular suit.'" *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 191 (3d Cir. 2001). A case of such "magnitude and complexity" that it "could not be tried" may not be certified. *Id.*

This is such a case. Plaintiffs proposed a three-phase trial in which all the economic-loss claims for both consumers and TPPs would "be jointly prosecuted in a single trial with a jury making findings on the legal claims, and the [c]ourt making findings on the equitable claims." (D.1748-23, 3.) If necessary, a second phase would "determine the aggregate amount of non-compensatory damages and/or civil penalties," a third phase would apportion damages, and a claims-administration process would allocate recovery. (*Id.* 6-8.)

A trial of this magnitude would be unmanageable at every stage. First there is the trial itself, which would involve 111 subclasses—so many that it took the

plaintiffs *67 pages just to list them*. (*See* D.1747-1; D.1747-2.) These subclasses advance five legal theories against 28 defendants from 10 different corporate families, spanning four different levels of the supply chain—API manufacturing, finished-dose manufacturing, wholesale and retail.[6] Dizzying numbers of witnesses and trial days are guaranteed, as are juror confusion and trial error.

Instructing the jury would be even more complicated. As other courts have held, "[i]f more than a few of the laws of the fifty states differ, the district judge would face an impossible task of instructing a jury." *In re Am. Med. Sys.*, 75 F.3d 1069, 1085 (6th Cir. 1996). The task in this case would be orders of magnitude beyond "impossible." The model jury instructions applicable to plaintiffs' claims total approximately *1,200 pages*. (*See* D.2008-12, D.2008-13, D.2008-14, D.2008-15.) At a quick pace, reading one page every two minutes, it would take *40 hours*—a whole workweek—to instruct the jury. Once instructed, no human jury could possibly account for the "nuances" of the "multiple standards" and return an intelligent verdict. *Marshall v. H&R Block Tax Servs.*, 270 F.R.D. 400, 408 (S.D. Ill. 2010); *see also, e.g.*, *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 2:06-cv-1833, 2015 WL 3623005, at *40 (E.D. Pa. June 10, 2015) (denying certification of

[6] The district court also overlooked jurisdictional and venue barriers to trying claims in 73 of the 93 consumer subclasses. *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). (D.2008, App. O.)

consumer and TPP class in part because "[p]laintiffs … failed to demonstrate how the jury could be instructed in a manageable and accurate fashion").[7]

Strikingly, plaintiffs conceded these manageability issues in their briefing below, encouraging the district court to "devise imaginative solutions" to rescue the massive classes. (D.2057, 5.) Among other things, plaintiffs suggested that the court could "sever a specific subclass or issue class or a discrete trial" or "advanc[e] … discrete groupings or subclasses by defendant, state(s), claims, or issues." (*Id.* 4.) They even suggested that the classes could exist for pretrial purposes only, followed by "severing and remanding [individual] cases." (*Id.* 9.)

The district court did not even mention plaintiffs' concession in its ruling; nor did it clarify whether it envisioned a single trial or some alternative procedure. To the extent it mentioned manageability, it waved the issue off, vaguely conceding that trial might be "onerous and [require] a steep climb of effort," but that the district court's "experience with the MDL" will guide the way. (Opinion 24.) In truth, nothing in the district court's experience equips it for the epic proceeding that awaits. And accepting the district court's "everything goes in an MDL" rationale would effectively dispense with Rule 23's requirements in

[7] The district court's extensive tables and comments on the parties' state-law appendices illustrate the complexity of the issues and the impossibility that a jury receiving a week's worth of oral instructions could ever keep them straight.

multidistrict litigation—an approach other appellate courts have condemned. *E.g.*, *Nat'l Prescription Opiate Litig.*, 976 F.3d at 673. In reality, the only explanation for the court's ruling is that it does not actually envision any class trial at all. Like its refusal to hold bellwether personal injury trials (as sought by defendants), the district court certified this class to exert more settlement pressure on defendants, and not because it believed a class trial was feasible consistent with the requirements of Rule 23 and its due process underpinnings. That is not permissible under Rule 23 or consistent with the role and obligations of an MDL judge.

CONCLUSION

For the forgoing reasons, the Court should grant the petition and reverse the class certification order.

Dated: February 22, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this petition complies with the type-volume limitation of Fed. R. App. P. 5(c) because it contains 5,188 words, as counted by Microsoft Word, the word processing software used to prepare this brief.

This petition also complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) & (6) because it has been set in a 14 point, proportionally spaced typeface (Times New Roman).

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CERTIFICATE OF BAR MEMBERSHIP

I certify, pursuant to Local Appellate Rule 46.1, that I am a member in good standing of the Bar of the United States Court of Appeals for the Third Circuit.

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CERTIFICATE OF SERVICE

I certify that, on February 22, 2023, I filed the foregoing Rule 23(f) Petition for Permission to Appeal, with the Clerk of the Court using the CM/ECF system. A true and correct copy was sent via electronic mail per agreement of the parties to the following counsel of record:

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EXHIBIT 1

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

***In re*: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION**	Master Docket No. 19-2875 (RBK/SAK)
	Opinions on Certification of Proposed Classes under FRCP *Rule* 23 and on Class Certification Expert Reports under *FRE* 702
This Document Applies to All Actions	

KUGLER, United States District Judge:

Before the Court in this multidistrict litigation ("MDL" or "Valsartan MDL") are several motions:
from All plaintiffs: a motion to certify two economic loss classes, each having a number of subclasses, as well as medical monitoring classes; and
from Third Party Payor ["TPP"] plaintiffs: a separate motion to certify a TPP economic loss class.

In addition to these are motions from both defendants and plaintiffs seeking to preclude the reports of the class certification experts of the opposing party.

Table 1 lists the outstanding plaintiffs' motions for class certification and the motions to preclude that this opinion resolves. An Order of this date accompanies this Opinion.

The Valsartan MDL arose from an extensive Food and Drug Administration ["FDA"] recall in the U.S. of generic hypertensive, prescription drugs ["Valsartan" or "Valsartan-containing drugs" or "VCDs"]. To be clear, as used herein, the term "VCD" refers to valsartan-containing drugs that were contaminated with probable genotoxic human carcinogens in the form of nitrosamines, N-nitrosodimethylamine ("NDMA") and N- N-nitrosodiethylamine ("NDEA").

Beginning in July 2018 and upon the FDA's discovery that VCDs sold in the U.S. were contaminated with these nitrosamines, the FDA continued to recall VCDs into 2021. The recalls concerned VCDs manufactured and/or finished into pills by several defendants not headquartered in the U.S., including: in China: Zhejiang Huahai Pharmaceuticals Ltd.["ZHP"]; in India: Mylan Pharmaceuticals Ltd. ["Mylan"]; Aurobindo Pharmaceuticals Ltd.["Aurobindo"]; Hetero Pharmaceuticals Ltd. ["Hetero"]; and Torrent Pharmaceuticals Ltd. ["Torrent"]; and in Israel: Teva Pharmaceuticals ["Teva"]. Most of the foreign drug manufacturers also have U.S. subsidiaries that either put the drugs in finished form or sold/distributed them in the U.S.

Table 1: Motions This Opinion Resolves

ECF No.	Movant	Relief Sought
1747	All Plaintiffs	Motion to Certify Consumer Economic Loss Class, and to Certify Third Party Payor Class, and to Certify Medical Monitoring
1749	Third Party Payor Plaintiffs	Motion to Certify Third Party Payor Class
2024	Defendants	Motion to Preclude Report of Plaintiffs' Class Expert, Edward Kaplan, M.D.
2032	Defendants	Motion to Preclude Report of Plaintiffs' Class Expert, Zirui Song, M.D., PhD
2033	Defendants	Motion to Preclude Report of Plaintiffs' Class Expert, Ron Najafi, PhD
2034	Defendants	Motion to Preclude Report of Plaintiffs' Class Expert, Kaliopi Panagos, PharmD, RPh
2035	Defendants	Motion to Preclude Report of Plaintiffs' Class Expert, John Quick, MBA
2036	Plaintiffs	Motion to Preclude Report of Defendants' Class Expert, Eric Sheinin, PhD
2037	Wholesaler Defendants	Motion to Preclude Report of Plaintiffs' Class Expert, Rena Conti, PhD
2038	Plaintiffs	Motion to Preclude Report of Defendants' Class Expert, David Chesney
2040	Defendants	Motion to Preclude Report of Plaintiffs' Class Expert, Rena Conti, PhD
2041	Plaintiffs	Motion to Preclude Report of Defendants' Class Expert, Punam Keller, PhD
2043	Plaintiffs	Motion To Strike New And Altered General Causation Opinions of Defendants' Expert Michael Bottorff, PhD
2044	Plaintiffs	Motion to Preclude Report of Defendants' Class Expert, William Lambert, Ph.D.
2045	Plaintiffs	Motion to Preclude Report of Defendants' Class Expert, Mark Robbins, PhD
2046	Plaintiffs	Motion to Preclude Report of Defendants' Class Expert, Lauren Stiroh, PhD
2047	Plaintiffs	Motion to Preclude Report of Defendants' Class Expert, Jason Clevenger, PhD
2048	Plaintiffs	Motion to Preclude Report of Defendants' Class Expert, Timothy Kosty, MBA, RPh
2069	Defendants	MOTION for Leave to File Instanter Sur-reply Briefs In Further Opposition To Plaintiffs Motions For Class Certification, And Request For A Class Certification Hearing

The COURT HAVING REVIEWED the parties' submissions without a hearing in accordance with *Loc.R. 78.1 (b)*, for the reasons stated below, and for good cause shown,

THE COURT ORDERS regarding the motions to preclude, or strike, the reports of the parties' class certification experts:

Plaintiffs' Motion to Strike (ECF. No. 2043) New and Altered General Causation Opinions in the Report at ECF No. 2084, Exh. 2 of Michael Bottorff, PharmD is **GRANTED**, and in particular the following opinions of Dr. Bottorff are precluded:

1. "Oral doses at the levels detected in the generic valsartan at issue in this litigation are

metabolized in the liver almost completely, **preventing** exposure to other tissues and organs" (Bottorff Class Certification Report at 48:761-762);

2. "NDMA/NDEA in valsartan **will not reach systemic circulation**" (Bottorff Class Certification Report at 47: 779); and
3. "DNA repair mechanisms in humans can be as much as 10 times higher than that in rats, indicating a more active DNA repair in humans compared to rats" (Bottorff Class Cert. Report at 52:830-831).

Plaintiffs' Motion to Preclude (ECF No. 2038) the Class Certification Report of David Chesney, BA, MSJ, is **GRANTED IN PART AND DENIED IN PART.** Only Mr. Chesney's opinions on page 5 and immediately following in his Class Certification Report and which are limited to the issue of ZHP's compliance with FDA current Good Manufacturing Practices and based solely on his review of ZHP documents have been considered here. The opinions and discussion in the rest of Mr. Chesney's report have been precluded.

Plaintiffs' Motion to Preclude (ECF No. 2047) the Class Certification Report of Jason Clevenger, PhD, is **GRANTED**.

Plaintiffs' Motion to Preclude (ECF No. 2041) the Class Certification Report of Punam Keller, PhD, is **GRANTED IN PART AND DENIED IN PART**. Dr. Keller's opinions on pages 30 to 45 in her Report have been precluded. Her opinions regarding scholarly literature on consumer health decision-making in pages 1-29 of her Report have been considered but only to the extent that these opinions are based on actual consumer surveys and real world consumer research.

Plaintiffs' Motion to Preclude (ECF No. 2048) the Class Certification Report of Timothy Kosty, RPh, MBA, is **GRANTED IN PART AND DENIED IN PART**. The information and opinions in pages 49-99 of Mr. Kosty's Report have been precluded. Mr. Kosty's discussion of the workings of the U.S. pharmaceutical industry in pages 15-48 of his Class Certification Report has been considered.

Plaintiffs' Motion to Preclude (ECF No. 2044) the Class Certification Report of William Lambert, PhD, is **GRANTED IN PART AND DENIED IN PART.** The following opinions in Dr. Lambert's Report have been precluded:

- Dr. Lambert's opinion about the "worthlessness" of the VCDs, couched in terms of bioequivalence, is an unqualified economics opinion,
- Any of Dr. Lambert's opinions that the FDA's Orange Book does or not establish / create manufacturer warranties. By excluding these opinions of Dr. Lambert's, the Court is not expressly deciding one way or another whether the Orange Book creates manufacturer warranties; rather, the

Court finds that Dr. Lambert is not a legal expert qualified to opine on such an issue.

- Any of Dr. Lambert's opinions that plaintiffs failed to apply correct standards in determining for bioequivalence and pharmaceutical equivalence.
- Dr. Lambert's opinions at ¶38 of his Class Certification Report; and
- Dr. Lambert's opinions at ¶88 and ¶90 of his Class Certification Report.

Any other of Dr. Lambert's opinions in his Report has been considered.

Plaintiffs' Motion to Preclude (ECF No. 2045) the Class Certification Report of Mark Robbins, PhD, JD is **DENIED.**

Plaintiffs' Motion to Preclude (ECF No. 2036) the Class Certification Report of Eric Sheinin, PhD is **GRANTED IN PART AND DENIED IN PART.** Paragraph 69, and paragraphs 79 to 102 in Dr. Sheinin's Report have been precluded. Paragraphs 25 to 68, and paragraphs 70-78 in Dr. Sheinin's Report have been considered but only as BACKGROUND information, and NOT as reliable expert opinion on class certification, liability, damages, etc. issues.

Plaintiffs' Motion to Preclude (ECF No. 2046) the Class Certification Report of Lauren Stiroh, PhD is **DENIED.**

Defendants' Motions (ECF Nos. 2040 ["General Motion"] and 2037 ['Wholesalers Motion"]) to Preclude the Class Certification Report of Rena Conti, PhD are **DENIED.**

Defendants' Motion to Preclude (ECF No. 2033) the Class Certification Report of Ron Najafi, PhD is **GRANTED.**

Defendants' motion to Preclude (ECF No. 2035) the Class Certification Report of John Quick, MBA, is **GRANTED IN PART AND DENIED IN PART**. Mr. Quick's opinions on pp. 6-7 of his Report regarding the terms "adulterated" and "misbranded" and whether the VCDs were "adulterated" and "misbranded" have been precluded; the other opinions in Mr. Quick's Report have been considered.

Defendants' Motion to Preclude (ECF No. 2034) the Class Certification Report of Kaliopi Panagos, PharmD and RPh, is **GRANTED IN PART AND DENIED IN PART.** Dr. Panagos's opinions at paragraphs 47, and 52-59 in her Report and in the Summary of Opinions on page 10, paragraphs: B, D, G – I have been precluded. Her opinions at paragraphs 1 to 46, 49-51 and 54 in her Report and in the Summary of Opinions on page 10, paragraphs: A, C, E, and F have been considered.

Defendants' Motion to Preclude (ECF No. 2024) the Class Certification Report of Edward Kaplan, MD, is **DENIED**.

Defendants' Motion to preclude the Class Certification Report of Zirui Song, MD, PhD is **GRANTED IN PART AND DENIED IN PART**. Dr. Song's his opinions on a methodology for calculating

in a similar way the spend for medical monitoring services in pages 22 through 26 of his Report have been precluded. His discussion of background information in pages 8 through 21 in his Report has been considered.

THE COURT FURTHER ORDERS:

Plaintiffs' Motion to certify the Consumer Economic Loss Class is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 3 herein;

Plaintiffs' Motion to certify the Third Party Payor Class is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 4 herein;

Plaintiffs' Motion to certify the *Rule 23(b)(3)* Class of Medical Monitoring as an Independent Claim ["*Rule 23(b)(3)* IND MedMon Class"] is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 7 herein;

Plaintiffs' Motion to certify the *Rule 23(b)(2)* Class of Medical Monitoring as an Independent Claim ["*Rule 23(b)(2)* IND MedMon Class"] is **DENIED without prejudice.** The Court **GRANTS** plaintiffs the option to re-seek class certification of this class by briefing on the specific estoppel effects this class may have on the other two certified Medical Monitoring classes;

Plaintiffs' Motion to certify the *Rule 23(b)(2)* Class of Medical Monitoring as a Remedy is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 7 herein; and

THE COURT FURTHER ORDERS:

Defendants' Motion (ECF No. 2069) for leave to file instanter sur-reply briefs in further opposition to plaintiffs motions for class certification, and Request for a class certification hearing is **DENIED** as made moot by this Opinion.

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1.0 BACKGROUND

In this MDL, plaintiffs allege that contamination with probable carcinogens of the generic hypertensive medicine titled Valsartan resulted from defendants' violations not only of state law but also of good manufacturing practices ("cGMPs") that the FDA, under the Food Drug and Cosmetic Act ["FDCA"], demands of drug manufacturers in making drugs sold in the U.S. It is the FDA-issued Guidances that spell out to foreign and domestic drug manufacturers alike those obligatory cGMPs they must follow in order to ensure the FDA-required integrity, quality, and safety of active pharmaceutical ingredients ["API"] and finished dose products ["FD"] sold in the U.S.

Based on their allegations of state law and cGMP violations, plaintiffs seek certification under *Fed. R. Civ. Proc. 23* of two categories of classes: Economic Loss classes of plaintiffs and their insurers who together paid for the VCDs; and Medical Monitoring classes of plaintiffs for the detection of any developing cancer advanced by their ingestion of VCDs. Plaintiffs seek two economic loss classes: first, a class of consumers who paid at least in part for the VCDs they ingested, hereinafter the "ConEcoLoss" class. Within the ConEcoLoss class, plaintiffs seek 93 separate subclasses, subdivided according to the variation in state law standards for each of the 5 claims: 1) breach of express warranty; 2) breach of implied warranty; 3) fraud; 4) state consumer law protection act; and 5) fraud. *See* ECF No. 1747, Exh. A.

Plaintiffs' second economic loss class comprises Third Party Payors, such as insurers, that either paid for or reimbursed the consumers who were their insureds for the ingested VCDs, hereinafter the "TPPEcoLoss" class. The class is subdivided into 19 subclasses according to the variation in state law standards, again, for each of the 5 claims: 1) breach of express warranty; 2) breach of implied warranty; 3) fraud; 4) state consumer law protection act; and 5) fraud. *See* ECF No. 1747, Exhibit B.

Specifically, the economic loss classes, including the 93 ConEcoLoss subclasses and the 19 TPPEcoLoss subclasses rest on the following state law claims:

1) express warranty claims against the manufacturer defendants ["mfrs"];
2) implied warranty claims against the mfrs and the retail pharmacy defendants ["Pharmacies"];
3) common law fraud claims against the mfrs;
4) consumer state protection act claims against the mfrs and the Pharmacies; and
5) unjust enrichment claims against the wholesaler defendants ["Wholesalers"] and retailers ["Pharmacies"].

Besides the economic loss classes, plaintiffs also seek from all defendants[1] three medical monitoring classes: one class in certain U.S. jurisdictions under *Rule 23(b)(3)* where medical monitoring is an independent claim for damages; an alternative class in those same jurisdictions under *Rule 23(b)(2)*

[1] The Medical Monitoring Plaintiffs have asserted class claims against numerous Active Pharmaceutical Ingredient ("API") Manufacturers, Finished Dose ("FD") Manufacturers, three Wholesalers Defendants, and eight Retail Pharmacy Defendants.

where medical monitoring is an independent claim for an injunctive remedy; and a *Rule 23(b)(2)* class in virtually all U.S. jurisdictions where medical monitoring is an injunctive remedy for an accompanying independent claim. These classes are termed "MedMon". Each of the MedMon classes comprise consumers who are currently cancer-free but who have ingested an estimated lifetime cumulative dosage ["LCD"] of NDMA and/or NDEA from their VCDs and, because of that, may have an increased risk, and be more susceptible, to developing certain cancers.

Plaintiffs seek the *Rule 23(b)(3)* or *Rule 23(b)(2)* independent-claim MedMon classes in U.S. jurisdictions that allow it by state law. They seek the *Rule 23(b)(2)* remedy-claim MedMon class in U.S. jurisdictions that define medical monitoring as ancillary relief to one or more of the following, independent causes of action: (1) negligence; (2) negligence per se; (3) negligent misrepresentation and omission; (4) medical monitoring; (5) products liability – manufacturing defect; (6) failure to warn; (7) breach of implied warranty of merchantability; (8) breach of express warranty; (9) fraud and fraudulent concealment; and (10) claims under state law product liability acts. See ECF No. 1747, at Appendix C and ECF No. 1750: 3 fn. 3.

Apropos the motions to preclude are declarations from several experts (hereinafter "expert reports") on class certification issues such as economic worthlessness of the contaminated VCDs, the therapeutic value of the VCDs, the purportedly actionable conduct of: the mfrs and Pharmacies—that support claims of breach of warranty, fraud, and consumer protection violation—and of the Wholesalers and Pharmacies —that support unjust enrichment claims for sales of worthless VCDs. The parties have filed motions under *Fed. R. Evid.* ["*FRE"*] *702* to preclude the testimony of their opponents' class certification experts. This opinion decides the parties' motions to preclude the testimony of the class certification experts. Tables 8 and 9 in Section 6.0 lists these motions.

The Court knows the parties are well aware of the background of the MDL, its procedural history, and discovery challenges and foregoes an exposition of these here, but recommends a review of these, ECF Nos. 675, 728, 775, 818, 839, 1019, 1753, 1811, 1825, 1838, 1958, 1974, and 1994, if a refresher is needed.

2.0 GENERAL LEGAL STANDARDS UNDER *FED.R.CIV.P. 23*

Fed.R.Civ.P. 23 delineates the legal standards by which a Court certifies classes. To get certified, a proposed class must satisfy all four requirements of *Rule 23(a)*[2] and at least one of those of *Rule 23(b)*.[3] *See Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 613–614 (1997); *see also Barnes v.*

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[2] *Rule 23 (a)* states: One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

[3] *Rule 23 (b)* states: An action may be maintained as a class action if the prerequisites of subdivision (a) are satisfied,

American Tobacco Co., 161 F.3d 127, 140 (3d Cir.1998). As movants, the plaintiffs have the burden of proof to show the classes should be certified. B*aby Neal v. Casey*, 43 F.3d 48, 55 (3d Cir.1994); D*avis v. Romney*, 490 F.2d 1360, 1366 (3d Cir.1974). While plaintiffs have no obligation to "prove" the merits of their case at this stage, *Rule 23* nonetheless demands a Court's higher-order review than done for a pleading standard. *Wal–Mart v. Dukes et al.*, 564 U.S. 338, 350 (2011). A District Court's certification of a class may necessitate that it makes factual findings and legal conclusions that overlap with and pertain to the underlying merits of the suit (*Id*. at 350-351), all of which must be supported by a preponderance of the evidence. *In re Hydrogen Peroxide Litig.*, 552 F.3d 305, 317 (3d Cir.2008, *as amended* 2009). That is, while limited to determining whether *Rule 23* requirements are met (*See, e.g., Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 177 (1974)), a court's class certification analysis may nonetheless need to probe beyond the pleadings (N*ewton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 166–67 (3d Cir.2001)) into a review of the substantive elements of the proposed class members' arguments in order to shape a proper legal landscape at trial.

The Third Circuit has called upon its district courts to conduct a thorough-going, rigorous class certification analysis (*Mielo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 483 (3d Cir. 2018) [*overruling* the once-relaxed class certification standard in this Circuit]; *see also Beck v. Maximus, Inc.*, 457 F.3d 291, 297 (3d Cir.2006)), encouraging them not to approve proposed classes easily. *Mielo,* 897 F.3d at 483. Since the district court exercises its full discretion under *Rule 23* to certify a class (*Beck*, 457 F.3d at 297), if certification is found warranted, the district court's certification order must clearly spell out the claims, issues or defenses subject to class treatment. *Wachtel v. Guardian Life Ins. Co. of America*, 453 F.3d 179, 184 (3d Cir.2006); *Rule 23(c)(1)(B)*. In short, the district court determines if class certification is proper by reviewing the pertinent facts and applying them to each requirement of *Rule 23(a) and 23(b).*

3.0 CONSUMER ECONOMIC LOSS CLASS CERTIFICATION

3.1 CLASS DEFINITION AND PARTIES ALLEGATIONS

Plaintiffs seek to certify an economic loss class, herein **ConEcoLoss**, that comprises consumers

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and in addition:
(1) the prosecution of separate actions by or against individual members of the class would create a risk of
(A) inconsistent or varying adjudications with respect to individual members of the class which would establish incompatible standards of conduct for the party opposing the class, or
(B) adjudications with respect to individual members of the class which would as a practical matter be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests; or
(2) the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole; or
(3) the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action.

who paid in whole or in part for contaminated VCDs filled upon U.S. prescriptions and sold to them in the U.S. during the relevant period, i.e., from about 2012 up to and including the last recall of 10 November 2021. Plaintiffs divide the ConEcoLoss class into 93 subclasses or groupings according to the state law requirements for each element of each of the five following claims: breach of express warranty against Manufacturers; breach of implied warranty against Manufacturers and Retailers; common law fraud against Manufacturers; state Consumer Protection Act Violations; and unjust enrichment against Wholesalers and Pharmacies.

Table 2 lists the five claims alleged against defendants by the proposed economic loss classes (ConEcoLoss and TPPEcoLoss) and summarizes the Court's findings as to whether each *Rule 23* requirement is met for each claim. The five claims in both proposed economic loss classes against various defendants are:

1) breach of express warranty against Manufacturers. The required elements of this claim may include variously privity with the mfr, and/or pre-suit notice to the mfr, and other elements;
2) breach of implied warranty against Manufacturers and Retailers. The required elements of this claim may include variously privity with the mfr and seller, and/or pre-suit notice to the mfr and seller, as well as other elements.
3) common law fraud against Manufacturers; The required element of this claim includes varying levels of knowledge of deception, ranging from ignorance of it, or recklessness about it, or knowledge of it, as well as other elements.
4) State Consumer Protection Act violation. The required elements may include lack of intent, pre-Suit Notice, FTC-guided Language, and others.
5) Unjust Enrichment against Wholesalers and Pharmacies. The required elements include unjust burden level; defendants' receipt of direct benefit; and others.

The Court's strategy for determining whether to certify the proposed economic loss classes—for each claim has been two-fold and interdependent:

1) a generalized, higher-level review of the parties' arguments relative to each *Rule(a) and (b)* requirement to see if the class as a whole meets *Rule 23*; and

2) in-depth, detailed research into the legal propriety of plaintiffs' proposed subclasses by scrutinizing the caselaw in each jurisdiction for each required element of each claim and then confirming or correcting plaintiffs' proposed subclasses for a particular jurisdiction.

This process has been iterative.

TABLE 2: *Rule 23* Findings for the Economic Loss Classes: Consumer Economic Loss and Third Party Payor Economic Loss

Specific Claims	*23(a)(1)* Numerosity	*23(a)(2)* Commonality	*23(a)(3)* Typicality	*23(b)(4)* Adequacy	*23(b)(3)* Predominance	*23(b)(3)* Superiority	*23(b)(3)* Ascertainability
Mfrs: *Express Warranty Breach* - Variable state law req'ts = Pre-Suit Notice; Privity; & Others	Met	Met	Met	Met	Met	Met	Met
Mfrs & Retailers: *Implied Warranty Breach* - Variable state Law req'ts = Pre-Suit Notice; Privity; & Others	Met	Met	Met	Met	Met	Met	Met
Mfrs: *Fraud* – Variable state law req'ts = Ignorance of Deception; OR Recklessness of it:, OR Know-ledge of it; & Others	Met	Met	Met	Met	Met	Met	Met
Mfrs & Retailers: *State Consumer Protection*-Variable state law req'ts = Intent; Pre-Suit Notice; FTC-guided Language; & Others	Met	Met	Met	Met	Met	Met	Met
Wholesalers & Pharmacies: *Unjust enrichment*- Variable state law req'ts differ for different defendants = Unjust Burden Level; Defendants' Receipt of Direct Benefit; and Others.	Met	Met	Met	Met	Met	Met	Met

3.2 *RULE 23(a)* REQUIREMENTS

Defendants assert the ConEcoLoss proposed class meets no *Rule 23(a)* or (*b)* requirement.

3.2.1 ConEcoLoss Class: *Rule 23(a)(1)* - Numerosity

Rule 23(a)(1) requires a class to be "so numerous that joinder of all members is impracticable." *Hayes v. Wal–Mart Stores, Inc.*, 725 F.3d 349, 354, 356 (3d Cir. 2013) [*quoting 23(a)(1)*]; *Mielo,* 897 F.3d at 484. Although determined on a case-by-case basis, numerosity is met when the potential number of plaintiffs in the proposed class action exceeds 40. *Marcus v. BMW of N. Am., LLC,et al.*, 687 F.3d 583, 595 (3d Cir. 2012) [*quoting Stewart v. Abraham*, 275 F.3d 220, 226-227 (3d Cir. 2001)]. In this MDL, Pharmacies' own data show valsartan prescriptions attributed to defendant API or finished dose manufacturers number in the millions. Accordingly, the Court finds this requirement met.

3.2.2 ConEcoLoss Class: *Rule 23(a)(2)* - Commonality

Rule 23(a)(2) requires there be questions of law or fact common, but not necessarily identical, to all members of the proposed class. *Reyes v. Netdeposit*, LLC, 802 F.3d 469, 486 (3d Cir.2014). To satisfy this requirement, "even a single common question will do". *Wal–Mart Stores, Inc.*, 564 U.S. at 357; *see also Rodriguez v. Nat'l City Bank*, 726 F.3d 372, 382 (3d Cir.2013). Specifically, class members must assert a common contention capable of class-wide resolution, the truth or falsity of which is "central to the validity of each one of the claims in one stroke." *Mielo,* 897 F.3d at 489–90 [*quoting Wal-Mart*, 564 U.S. at 350]; *see also Marcus*, 687 F.3d at 597.

Plaintiffs maintain the commonality critical to the class and which relates to each putative class members' claims is that defendants' tortious conduct caused the contamination of the ingested VCDs.

Defendants assert that plaintiffs cannot demonstrate commonality of facts and legal issues of the proposed class members because each putative member ingested one or more of possibly hundreds of different VCDs that made or finished by different defendants, with each VCD having different alleged levels of impurities, if any. Thus, putative class members have individualized facts relating to the VCDs they ingested, the dosages, and duration of ingestion. Defendants also assert that different VCDs had different costs, which implicates a different damages amount for each class member, thereby eroding a commonality of economic loss across the class and requiring individualized loss calculations. From the testimony of the named class representatives, defendants point to a logical conclusion that unnamed class members must have received varying levels of benefits and likewise made varying choices about continued ingestion after learning of the recall, all of which variability not only disqualifies class certification but precludes a class-wide trial.

Defendants do not consider *Mielo's* guidance: that commonality translates into a common contention by all named and unnamed putative plaintiffs regarding the conduct that is attributable to their injury. Defendants do not dispute the contention that it is defendants' conduct of contaminating the VCDs that caused plaintiffs' economic loss, however varied the facts relating to each putative member's economic loss.

Moreover, as for defendants' argument that the ConEcoLoss class is replete with facts relating to individualized VCDs, dosages, durations, and decisions to risk continued ingestion, plaintiffs' subdivision of the class into 93 subclasses goes a considerable way to account for these individual details. Plaintiffs' groupings are based on state law requirements of the elements of each of the 5 claims: warranties, fraud, consumer protection, and unjust enrichment. In this Circuit, subdividing a class of members having individualized facts into groupings that account for these facts according to state law standards moves the needle toward a showing of commonality. *See e.g. Chen v. Amtrak* , No. 18-cv-3617, 2019 WL 5294419 at * 9 (E.D. Pa. 18 Oct 2019).[4] Accordingly, the Court finds this requirement met.

3.2.3 ConEcoLoss Class: *Rule 23(a)(3)* – Typicality

"Typicality entails an inquiry whether 'the named plaintiff's individual circumstances are markedly different or … the legal theory upon which the claims are based differs from that upon which the claims of other class members will perforce be based…. Factual differences will not render a claim atypical if the claim arises from the same event or practice or course of conduct that gives rise to the claims of the class members, and if it is based on the same legal theory." *Baby Neal v. Casey*, 43 F.3d 48, 57-58 [internal quotations and citations omitted]. Aptly, the Third Circuit has recognized that typicality centers on whether the interests of the named plaintiffs align with those of the unnamed members (*Stewart*, 275 F.3d at 227) and, explicitly, whether the claims and facts of class representatives are sufficiently like those of unnamed class members. *In re Schering Plough Corp. ERISA Litig.*, 589 F.3d 585, 597 (3d Cir. 2009). The Third Circuit has also seen that typicality and adequacy of representation tend to merge. *Baby Neal*, 43 F.3d at 56; *Beck v. Maximus, Inc.*, 457 F.3d 291, 296 (3d Cir. 2006) ["because both look to potential conflicts" [*quoting Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 626 n.20.

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[4] While the court in *Chen v. Amtrak* (No. 18-cv-3617, 2019 WL 5294419 at * 9 (E.D. Pa. 18 Oct 2019) recognized plaintiffs need only produce a "single common question" to meet the commonality requirement in *Rule 23(a)(2)*, it found the dissimilarities in the key facts of each individual's exposure to the sprayed chemical Round-Up® vitiated commonality (and predominance).

Although recognizing its own discretion in specifying subclasses and certifying the class as to certain common questions, the *Chen* court felt no obligation to do so and quoted the Third Circuit in *Reyes*, 802 F.3d at 494: "It is not the District Court that is to bear the burden of constructing subclasses. That burden is upon the plaintiff who is required to submit proposals to the court." *Chen*, 2019 WL 5294419 at *9.

Finding plaintiffs had put forth no potential subclasses and declining *sua sponte* to define subclasses on common questions, the *Chen* court ruled the commonality requirement of the proposed *Rule 23(b)(3)* class was not met.

The situation in *Chen* is NOT the situation here, where plaintiffs have structured the proposed 93 ConEcoLoss subclasses to line up with the elements of each claim in each jurisdiction.

(1997)].

In evaluating typicality, courts in this Circuit contrast the differences in legal theory and claims of the class representatives against those of the unnamed class members (*In re Schering Plough*, 589 F.3d at 597–98) as well as compare "the attributes of the [named] plaintiff, the class as a whole, and the similarity between the [named] plaintiff and the class." *Marcus*, 687 F.3d at 598. However, fact differences alone between the named and unnamed plaintiffs do not render a claim atypical so long as the named plaintiffs' claim arises from the same events, practices, or course of conduct of the defendants as for all class members, and is based upon the same legal theory." *Stewart*, 275 F.3d at 227–28 [*quoting Hoxworth v. Blinder, Robinson & Co.*, 980 F.2d 912, 923 (3d Cir. 1992)].

Boley v. Universal Health Services, Inc., 36 F.4th 124, (3d Cir.2022)[5] is a recent example of such a compare-and-contrast analysis. There plaintiffs alleged defendants had used a flawed process for funding an ERISA pension, which allegation girded each putative class member's claim. *Id*. at 134.

The extent of similarity in the allegations across the *Boley* class resembles that in the allegations of each ConEcoLoss plaintiff here. To the point, plaintiffs here allege defendants' conduct is attributable to the same kind of economic loss for all putative class members, to wit: either defendants' alleged lack of care in complying with FDAs Guidelines and cGMPs in executing the solvent extraction process for valsartan API, or their failure to confirm independently mfrs' compliance with such regulations resulted in contamination of each consumer's VCDs during the relevant period. Plaintiffs' allegations here have been met by the same, specific defense asserted by each category of defendant. Similarity of allegation for, and defense by, each class member shows that the legal interests of the named class representatives do not fundamentally conflict with those of unnamed class members. *See Boley*, 36 F. 4th at 134 [*stating* "So long as the alleged cause of the injury remains the same across all [], 'even relatively pronounced factual differences will generally not preclude a finding of typicality.' *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 311 (3d Cir. 1998) [*quoting Baby Neal v. Casey*, 43 F.3d 48, 58 (3d Cir. 1994)]."

Defendants argue the breakdown of the singular ConEcoLoss class into 93 subclasses--which plaintiffs assert nonetheless account for all the recognized variability in state law elements for each claim—is not refined enough and cannot account for the fact differences between plaintiffs such as dosage, duration of ingestion, payment options for the VCDs, amount of NDMA contamination, etc.

Fact differences no doubt exist among the consumer plaintiffs. Nonetheless, both named and unnamed consumer plaintiffs equally aver that economic loss arises from the same common course of defendants' conduct—contamination of the VCDs, which affected the integrity, purity, and quality of

[5] Where the Third Circuit expressly found typicality of all plaintiffs' claims involving the underfunding of pension plans across 13 separate investment funds having different vesting requirements, payback rates, etc., i.e. very particularized facts for each class member's pension.

the drug sold and its merchantability—and from the same common course of plaintiffs' conduct—paying in whole or in part for drugs plaintiffs did not know were contaminated. Again, the *Boley* Court's views are relevant: "The nature of these claims makes intra-class conflicts unlikely—it is difficult to imagine class members who have benefited from, or are content to pay, pointless [] fees." *Boley*, 36 F.4th at 136. Similarly, this Court finds it difficult to imagine that any plaintiff here, named or unnamed, would aver their purchase of contaminated VCDs was not to some extent "pointless" and at least a partial economic loss. Accordingly, the Court finds the typicality requirement met.

3.2.4 ConEcoLoss Class: *Rule 23(a)(4)* - Adequacy

Analysis of class adequacy (often linked with that of typicality) involves confirming the claims of the class representatives and their legal interests are aligned with those of the unnamed class members. *Dewey v. Volkswagen Aktiengesellschaft*, 681 F.3d 170, 183 (3d Cir. 2012). In order to fail this prong, a conflict between representative plaintiffs and the rest of the class "must be fundamental." *Id.* at 184. However, *Rule 23(a)(4)* does not demand plaintiffs prove a negative, i.e., an affirmative lack of conflict between named and unnamed plaintiffs. Moreover ,"[w]hat seems clear … is that a plaintiff, to satisfy her burden to show she is an adequate representative of a proposed class, need not present evidence of the sort one might expect at summary judgment." *Duncan v. Governor of Virgin Islands*, 248 F.4th 195, 212 (3d Cir.2022). Dissimilarities within the proposed class may, but not necessarily do, impede the generation of common answers among class members. *Wal-Mart*, 564 U.S. at 350. Class certification concerns not the raising of common questions, "but rather the capacity of a class-wide proceeding to generate common answers that likely drive the resolution of the claims." *Ibid.* [citation omitted].

Plaintiffs assert that the 46 representatives of the ConEcoLoss class and subclasses have sifted through the necessary discovery and documents and have been deposed sufficiently long enough to familiarize themselves with the litigation. Moreover, they aver the fact situations of these 46 do not fundamentally or logically differ from, or clash with, the facts of the unnamed class members. Each named counsel of the class representatives—MDL Co-Lead Counsels Ruben Honik, Esq., Conlee Whiteley, Esq., and John R. Davis, Esq.—has the requisite experience from both this MDL, and from past experience with other class action matters and/or with pharmaceuticals litigation to represent the named class members acceptably.

Defendants assert the proposed ConEcoLoss class fails the adequacy and typicality requirements because: (1) individualized questions of law predominate over common legal issues despite the complex sub-classing proposals; (2) the proposed class members' claims will turn on highly individualized questions of fact; and (3) the named class representatives cannot adequately represent

class members from other states.

The typicality prong has been discussed above and found met. To fail the adequacy requirement, differences of highly individualized questions of fact between any named plaintiff in a particular subclass and the unnamed subclass members must be fundamental, which the Court interprets as "critical" to plaintiffs' claims. Defendants' contention that differences in state laws may not track the subclasses as closely as plaintiffs say does not raise a clarion call of fundamental conflict even between class members from different jurisdictions. This finding arises from the Court's own review of the alignment of plaintiffs' tables of subclasses with jurisdictional differences in the required elements of each claim. *See infra* Table 3. Accordingly, the Court finds this requirement met.

3.3 *RULE 23(b)(3)* REQUIREMENTS

Having found the ConEcoLoss class meets the *Rule 23(a)* requirements, the Court's "thorough-going review" (as directed by *Mielo)* turns to *Rule 23(b)* requirements.[6] The proposed class may be analyzed under one of three enumerated categories of *Rule 23(b)*.[7] For both Economic Loss classes here, plaintiffs have sought certification under only *Rule 23(b)(3)*, not *23(b)(1)*[8] or *23(b)(2)*[9].

Under *Rule 23(b)(3)*, certification is appropriate when: (i) common questions of law or fact predominate over questions affecting the individual class members only; and (ii) class treatment is superior to other available methods of adjudication. *In re Thalomid and Revlimid Antitrust Litigation*, No. 14-cv-6997, 2018 WL 6573118 at *10 (D.N.J. 30 October 2018) [*citing Rule 23(b)(3); Boyle v. Progressive Specialty Ins. Co.*, No. 09-5515, 2018 WL 2770166, at *4 (E.D. Pa. 7 June 2018)]. Invoking class certification under *Rule 23(b)(3)* indicates the action seeks money damages for all class members because defendants allegedly have injured them in fundamentally similar ways. Besides demonstrating predominance and superiority, plaintiffs in the Third Circuit must also show that a *Rule 23(b)(3)* class is " "currently and readily ascertainable based on objective criteria' " *City Select Auto Sales Inc. v. BMW of N. Am. Inc.*, 867 F.3d 434, 439 (3d Cir. 2017) [*quoting Marcus,* 687 F.3d at 59.

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[6] Again, to be shown by a preponderance of the evidence. *In re Hydrogen Peroxide Antitrust Litig.*, 552 at 307 (3d Cir.2009).
[7] *See supra* note 3.
[8] *Rule 23(b)(1)* is typically a "Prejudice Class Action" and sought when litigating individual actions might create prejudice that a class action suit would avoid. Certification under 23(b)(1) requires the class action be a mandatory class action, that is, where absentee members cannot opt out of the class.
[9] *Rule 23(b)(2)* relates to certification of an Injunctive / Declarative Relief Class Action, which enjoins certain conduct by defendant(s) rather than seeks money damages. To properly invoke *23(b)(2)*, plaintiffs have to properly define the class and also show defendant's conduct applies to all putative class members of the class. Plaintiffs need not certify actual harm to each class member, only that possible harm to the entire class is attributable to defendants' unjust conduct. A *Rule 23(b)(2)* class commands mandatory entry for class members who have neither a mechanism to opt out, nor the need to be noticed, of their class membership.

3.3.1 ConEcoLoss Class: *Rule 23(b)(3)* - Predominance[10]

Predominance is confirmed when issues of law or fact common to the putative class members ground, summarize, and permeate their claims of injury and requests for damages, in short, when such common issues dominate the class members' claims. Particularized, dissimilar legal issues and facts applying in a fundamental way to individualized claims of the class members weigh against predominance and a *23(b)(3)* certification.

Although the *23(a)(2)* commonality and the *23(b)(3)* predominance requisites are closely linked, meeting the predominance prong is more demanding (*In re Hydrogen Peroxide*, 552 F.3d at 311) and in effect subsumes commonality. *Ferreras v. American Airlines, Inc.*, 946 F.3d 178, 185 (3d Cir. 2019) [*citing Danvers Motor Co., Inc. v. Ford Motor Co.*, 543 F.3d 141, 148 (3d Cir.2008)]. In weighing predominance, a court analyzes whether each element of a legal claim is "capable of proof at trial through evidence that is common to the class rather than [is] individual to its members." *In re Suboxone (Buprenorphine Hydrochlorine and Naloxone Antitrust Litigation*, 967 F.3d 264, 269-270 (3d Cir. 2020) [*quoting Marcus*, 687 F.3d at 600.]

Plaintiffs assert their proposed 93 subclasses meet both the predominance and the superiority requisites. Looking generally at plaintiffs' five claims-- breach of express and implied warranties, fraud, violation of consumer protection statutes, and unjust enrichment, the Court sees that, at a minimum, plaintiffs have to show that these facts apply to the entire class of ConEcoLoss plaintiffs:

1) the conduct of API mfrs violated certain current Good Manufacturing Practices (cGMPs) in FDA's Guidances in making valsartan API during the relevant period and that these violations resulted in the API contamination by nitrosamines, especially NDMA and NDEA;
2) that FD mfrs processed the contaminated API into contaminated valsartan pills of various dosages and forms, which Wholesalers purchased for sale and distributed in the United States.
3) Pharmacies obtained such contaminated valsartan pills and sold them to consumer plaintiffs in transactions in the United States.
4) defendants' conduct, whether intentional or not, encompassed a lack of testing of the API or finished dose products in the wake of cGMPs violations, which failure grounds and shores up the breach of warranty claims, the claims of violation of state consumer protection laws, as well as the fraud claims against the drug mfrs.
5) Wholesalers and Pharmacies were unjustifiably enriched from sales of the VCDs (in the

[10] *Rule 23(b)(3)* states: "A class action may be maintained if *Rule 23(a)* is satisfied and if:
the court finds that the questions of law or fact common to class members **predominate** over any questions affecting only individual members, and that a class action is **superior** to other available methods for fairly and efficiently adjudicating the controversy. [emphasis added].

U.S.) because the sales awarded these defendants a monetary benefit greater than the actual value of the contaminated drugs.

6) Plaintiffs contend, if the nitrosamine contamination were known at the time of sale, the VCDs would have been pulled from the market and unavailable for purchase, which made the VCDs worthless at the time of sale and which resulted in purchasers' economic loss and defendants' unjust enrichment.

In sum, plaintiffs argue their economic loss arises from the singular conduct of defendants throughout the U.S. drug supply chain, namely: that defendant-contaminated VCDs entered the U.S. drug supply chain by defendant downstream drug purveyors; that consumers bought the VCDs in the U.S. during the relevant period; and the relevant tortious conduct of each defendant in the U.S. drug supply chain applies to all purchasers[11] of the VCDs. Plaintiffs contend they have met *Rule 23(b)(3)* predominance because they have asserted that the conduct of each category of defendant contributed to making and selling contaminated VCDs in the U.S. and that if the contamination were known the VCDS would not have been sold and were therefore worthless on the date of sale. Summarily, plaintiffs argue the genotoxic contamination of VCDs and all the follow-on conduct that brought the VCDs into the U.S. market is what caused all VCD purchasers to experience an economic loss. Therefore, the facts and legal issues of purchasers' economic loss dominate and govern the 5 claims of breach of warranty, fraud, violation of consumer protection statutes, and unjust enrichment against the defendants, which demonstrates predominance.

Defendants do not address directly plaintiffs' contention that defendants' behavior of making and selling contaminated VCDs in the U.S. market created the singular and overarching legal justification for economic loss relief to U.S. consumers. Rather, they concentrate on the differences in the state law requirements of each of the five claims plaintiffs assert against them. Defendants also argue that the following facts are particular to each putative class member's purchase of VCDs and cannot be generalized across the putative class:

- each plaintiff's prescription called for a particular dosage;
- each plaintiff took the VCDs for a particular duration;
- the nitrosamine amount in the VCDs varied not only across a plaintiff's prescriptions over time but across prescriptions for different plaintiffs as well as across different lots and batches of VCDs, meaning that such fact variability negates the assumption that damages relating to breach of warranties and fraud occurred to each plaintiff and can be calculated uniformly across the class.

At heart, defendants argue that the nitrosamine levels of the VCDs differed sufficiently enough over

[11] As the following discussion on the certification of the third party payors class makes clear, purchasers of VCDs in the U.S. include not only consumers but their insurers who paid in full or in part for the drugs.

time to make it too uncertain to calculate an "expected" or "predictable" nitrosamine level that plaintiffs ingested and also a "predictable" level that did or may cause any genotoxic effects.

The Court notes these arguments inform largely on the problem of ascertainability of class members, discussed *infra.* Defendants may be hard pressed to refute that their conduct resulted in nitrosamine contamination of VCDs; it's incontrovertible that the FDA recalled lots and batches of presumed-contaminated VCDs for several years. It is further incontrovertible in the morass of factual and legal arguments here that the contamination resulted from defendants' non-compliance of cGMPs at some level. Since defendants' conduct in making contaminated VCDs and in putting these into the U.S. drug supply chain, which plaintiffs paid for, is incontrovertible, that singular fact grounds all of plaintiffs' claims. Put simply, because of defendants' conduct, plaintiffs have common facts upon which to base their economic loss claims and which are "capable of proof at trial through evidence that is common to the class rather than [is] individual to its members" (*In re Suboxone*, 967 F.3d at 269-270) and which dominate each putative class member's claims.

Especially because of defendants' arguments about the variation of state law elements that must be applied to such variable facts regarding dosage, duration, VCD ingested, nitrosamine concentration, etc., as stated above, the Court researched and reviewed the required elements for each of plaintiffs' five major claims in each proposed jurisdiction. The impetus for this research arose from Third Circuit guidance, especially from *In re Warfarin Sodium Antitrust Litigation,* 391 F.3d 516 (3d Cir.2004) and *In re National Football League Players Concussion Injury*, 821 F.3d 410 (3rd Cir 2016) summarized in the footnote.[12] Table 3 at the end of this section presents the results of this research,

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[12] *In re Warfarin Sodium Antitrust Litigation,* 391 F.3d 516 (3d Cir.2004) informs on the discretion a district court has, the way to wield it, and how to resolve whether fact variability defeats *Rule 23* in certifying a class where various state laws apply to putative class members who each have varying fact scenarios.

> "In certification of litigation classes for claims arising under the laws of the fifty states, we have previously noted that the district court must determine whether variations in state laws present the types of insuperable obstacles which render class action litigation unmanageable. *See Prudential,* 148 F.3d at 315; *see also In re Sch. Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir.1986). Thus, for instance, we have stated that **a district court should examine whether varying state laws can be grouped by shared elements and applied as a unit in such a way that the litigation class is manageable**. *Prudential,* 148 F.3d at 315; *In re Sch. Asbestos Litig.*, 789 F.2d [996] at 1010 [3d Cir.1986]." *In re Warfarin Sodium,* 391 F.3d at, 529. [emphasis added].
> . . . "In *Prudential,* we" ... "rejected an objector's contention that predominance was defeated because claims were subject to the laws of fifty states, *id.* at 315. Moreover, recent decisions elsewhere have certified nationwide or multistate classes under state laws in actions alleging overpayment for brand-name prescription drugs. *See In re Lorazepam & Clorazepate Antitrust Litig.*, 205 F.R.D. 369 (D.D.C.2002); *In re Synthroid Mktg. Litig.*, 188 F.R.D. 295 (N.D.Ill.1999). In certifying a nationwide settlement class, the District Court was well within its discretion in determining that variations between the laws of different states were insufficient to defeat the requirements of *Rule* 23." *In re Warfarin Sodium,* 391 F. at 530.

The Court in *In re National Football Players*, 821 F.3d 410 (3rd Cir 2016) found that the objectors had argued, as defendants here, that:

> "damage claims in a mass-tort class action such as this are too individualized to satisfy the requirements of predominance. They cite to *Amchem* [*Products, Inc. v. Windsor*, 521 U.S. 591] where, as we have discussed, a nationwide class of persons exposed to asbestos could not meet the predominance requirement. 521 U.S. at 624 [secondary citation omitted]. But *Amchem* itself warned that it does not mean that a mass tort case will never clear the hurdle of predominance." *Id.* at 625 [secondary citation omitted] ("Even mass tort cases arising from a common cause or disaster may, depending upon the circumstances, satisfy the predominance requirement."). *Id. at 434.*

These two Third Circuit cases give District Courts full discretion to find creative, practical pathways to get to the bottom of complicated class action motions, such as taking the initiative to examine if proposed subclasses resolve Rule 23(b)(3) and (2) requirements.

which shows that, for the most part, plaintiffs' proposed subclasses of this ConEcoLoss class account both for the variability in facts and the application of the facts to required elements of each claim.

Considering *In re Warfarin Sodium* while realizing its own research could help clarify variable "circumstances" as discussed *In re National Football Players*, the Court reviewed the correct legal standards for each of the five claims in each state for each of the proposed classes. And, to ensure plaintiffs bore their proper burden, the Court relied on defendants' oppositions of plaintiffs' subclasses under the assumption that defendants would have made every effort to confirm the correct legal standards. ECF No. 2008 (Attachments 7-11) (Appendices F through J). To be clear, the Court undertook its own independent research of the correctness of the standards for each claim in each jurisdiction in order to accommodate defendants' objections that plaintiffs had got the standards wrong or incomplete for certain claims under different state laws. That research has confirmed and corrects as needed plaintiffs' legally incorrect categorization of the ConEcoLoss subclasses. The results are detailed *infra* in Table 3. Plaintiffs are required to amend their 93 proposed subclasses to conform to the findings in Table 3.

Based on its research, the Court finds the *Rule 23(b)(3)* predominance standard has been met: there is a singular pleaded conduct—defendants' contamination of VCDs—which applies unilaterally to each consumer plaintiff in each subclass because each purchased the contaminated VCDs. The Court's correction of plaintiffs' subclasses serves to accurately map the variability of the legal standards for each claim and thus reduce the overall variability of individualized plaintiffs' legal issues. Put differently, the Court agrees that plaintiffs' naming subclasses that divide the ConEcoLoss class into smaller, even if numerous, groupings that track variability in legal issues is legally efficient and proper.

As a post-script to the predominance discussion above, the Court appreciates that various of the parties' experts opine on whether predominance of facts and law in plaintiffs' claims has been met. Both parties discount the predominance opinions of the opponents' experts, arguing the other parties' experts used unreliable methodology.

The Court looks to *In re Processed Egg Products Antitrust Litigation* ["*In re Processed Egg Products 2017*"],08-md-2002, 2017 WL 3494221, at *4-5 (E.D. Pa. 14 Aug 2017) as an example of relying on the predominance opinions of a class certification expert, even if that expert's methodology is flawed but reliable. The parties' dispute over reliable expert methodology arises from their opposing theories of damages by which to reimburse, if at all, consumers and TPPs for the contaminated VCDs. Plaintiffs contend defendants' conduct in contaminating the VCDs made the drugs worthless even before recall. That is, had the contamination been known, the VCDs would not have been sold and therefore VCD purchasers should be reimbursed the entire purchase price. Defendants argue plaintiffs' worthlessness theory is unreliable as sophomoric economics and lacking consideration of drug

purchasers' health rationales for continuing to ingest minimally contaminated drugs. At heart of this dispute is defendants' theory that if VCDs did have consumer value, then plaintiffs' legal claims of breach of warranty, fraud, etc. cannot possibly dominate across all consumers' and TPPs' demand for full purchase price damages.

In its predominance analysis here and for the TPPEcoLoss class, the Court has considered its conclusions on the reliability of the experts' reports set forth in Section 6.0; It has also heeded the guidance of *In re Processed Egg Products 2017.*[13] But It has NOT decided the predominance requirement of any *Rule 23(b)(3)* class based on its acceptance of either of the proposed economic loss theories. Since each parties' economic loss theory reduces or expands the importance of individualized fact questions over common ones, choosing one theory over the other drives a decision as to predominance that bounds too deeply into the province of the factfinder. Rather, the Court has chosen a practical approach to predominance: to confirm that subclasses aptly map the reality of state law variation and factual variability.

3.3.2 ConEcoLoss Class: *Rule 23(b)(3)* - Superiority

Rule 23(b)(3) requires a class action to be the superior method over "other available methods for the fair and efficient adjudication of the controversy" and sets forth several considerations in determining the superiority of the class action.[14] In practice, to meet this requirement, plaintiffs show the class action's superiority in terms of fairness and efficiency over that of other adjudication strategies. *In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 148 F.3d 283, 316 (3d Cir. 1998). Plaintiffs also must detail how unnamed members are to receive mandatory notice of the class as well as an opt-out right and procedure.

As this MDL includes a potentially large number of ConEcoLoss putative class members, to wit, millions of consumers (as well as potentially hundreds, if not thousands, of Third Party Payors ["TPPs"]), each consumer plaintiff seeks damages that are insignificant compared to the cost of prosecuting an individual lawsuit. An individual plaintiffs would have little economic interest to pursue their own separate action because the needed discovery, expert reports, and motion practice would be

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[13] To the extent that there is disagreement over the models …, the Court determines that question is best answered by a jury. *See In re Mushroom Direct Purchaser Antitrust Litig.*, No. 06-0620, 2015 WL 5767415, at *13 (E.D. Pa. July 29, 2015) [*concluding* that 'arguments about how the selection of data inputs affect the merits of the conclusions produced by an accepted methodology should normally be left to the jury.' [*quoting Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 808 (7th Cir. 2013)]]. "
In re Processed Egg Products, 08-md-2002, 2017 WL 3494221 at *5 (E.D. Pa. 14 Aug 2017)

[14] (a) interest of the class members in individually controlling the prosecution / defense of separate actions;
(b) extent and nature of any litigation concerning the controversy already commenced by or against members of the class;
(c) desirability or not of concentrating the litigation of the claims in the particular forum;
(d) the difficulties likely to be encountered in the management of a class action.

exorbitant in time and money. From the standpoint of both the ConEcoLoss members as well as the TPPEcoLoss members, a class action spreads the litigation costs among a very large class of injured parties and encourages private enforcement of state law. *See In re General Motors Corp. Pick-Up Truck Fuel Tank Products Liability Litigation*, 55 F.3d 768 , 784 (3d Cir.1995)

Moreover, this MDL, as a litigation mechanism, currently overrides any individual litigation efforts by putative ConEcoLoss and TPPEcoLoss members, up to the point of individual plaintiff trials.[15] As this Court has been the transferee court of this MDL since consolidation, four years ago, there can be little intelligent rationale for not concentrating the litigation efforts in this Court because of its fundamental experience with the issues and procedural history. Although managing a class action with 93 subclasses is likely onerous and a steep climb of effort, this Court's experience with the MDL weighs toward certification of the large ConEcoLoss class and its numerous subclasses. The MDL is undoubtedly the better mechanism for efficient adjudication and fairness because of the alleged singular cause of plaintiffs' economic loss and the resource-sharing of litigation efforts that benefits both the putative class members as well as the defendants. Accordingly, the Court finds this requirement met.

3.3.3 ConEcoLoss Class: *Rule 23(b)(3)* - Ascertainability

The Third Circuit has read into *Rule 23* an implicit two-prong requirement of ascertainability by which class members are identified.[16] Plaintiffs must articulate (1) an "objective" boundary definition of class membership and (2) workable method for confirming who is a class member and who is not. Specifically, "[i]n determining whether the ascertainability requirement is satisfied, [the District Court] must determine that the plaintiff has (1) 'defined [the class] with reference to objective criteria," and (2) identified a "reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.' *Byrd [v. Aaron's Inc.]*, 784 F.3d [154] at 163 [(3d Cir.2015), as amended 28 Apr 2015] (*quoting Hayes [v. Wal-Mart Stores, Inc*.,] 725 F.3d [349] at 355 [3d Cir.2013)]". *Kelly v. RealPage Inc*., 47 F.4th 202, 222 (3d Cir. 2022).

Kelly v. RealPage, 47 F.4th 202 (3d Cir. 2022)[17] is not only a very recent example of the balancing

[15] For the duration of the MDL, all individual lawsuits having the same claims as in the MDL must be transferred into the MDL.

[16] Not all Circuits agree that *Rule 23(b)(3)* requires ascertainability. Calling the Third Circuits' two-prong ascertainability test[16] "heightened",[16] the Second Circuit in *In re Petrobas* Securities, 862 F.3d 250, 265 (2nd Cir.2017) has stated "[s]uch a standard would upset the careful balance of competing interests codified in the explicit requirements of *Rule 23*", and stands with the Sixth, Seventh, Eighth, and Ninth Circuits in rejecting that *Rule 23* demands ascertainability.

[17] In *Kelly v. RealPage Inc.*, 247 F.4th 202, 222 (3d Cir. 2022), the Third Circuit reversed the District Court's decision that plaintiffs had not met the second prong of the ascertainability standard. Specifically, the District Court saw that identifying putative class members required the review of each individual's real estate file in order to confirm class membership, which It found too onerous and not administratively feasible. The Third Circuit was hard pressed to understand why.

The Circuit found the records of putative class members were kept in two separate databases, which used different software. There was no "unique identifier" in either database that could identify a putative class member. It would therefore be difficult to match records on

of competing, explicit interests of *Rule 23* but contains the Third Circuit's replete review of its own jurisprudence on ascertainability. As in *RealPage*, plaintiffs here have argued the first prong of ascertainability is met: the ConEcoLoss class can be objectively defined by an abundance of business records and data archived by different and various entities that track drug purchases in the U.S. Plaintiffs assert the primary piece of objective data that can identify putative class members is the National Drug Code ["NDC"].[18] Alternatively, plaintiffs can also use data from the Centers for Medicare & Medicaid Services (CMS), which has created an 11-digit NDC derivative that serves a similar function as the NDC. That the NDC (and derivative codes) record drug purchase information is axiomatically well-known and widely used in the pharmaceutical industry.[19] Moreover, Third Party Payors use this information to objectively identify purchased drugs for which they will reimburse their insureds.[20]

Plaintiffs also assert that each time a Pharmacy fills a prescription and sells the drug, the Pharmacy archives the transaction, which couples the transaction to the NDC, the consumer's name and particulars, price paid, insurance used, etc. Moreover, besides these pharmacy records, there are corresponding archives records for each filled script maintained by Pharmacy Benefit Managers ["PBMs"][21] as well as similar records archived by Health Insurers, which may be Third Party Payors in this litigation. Plaintiffs assert all of these the records from the Pharmacies, PBMs, and Health Insurers contain the same/similar essential information as well as other, ancillary information that help pinpoint the consumer and tie them to specific prescription-drug purchases.

In addition to this data kept in various formats and/or on various software systems by the Pharmacies, PBMs, and TPPs, transaction information is maintained by the mfrs about what drugs they sell to Wholesalers. This info is termed T3 data, which plaintiffs aver the Wholesalers maintain and

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request received via defendant's website with records requested from an external, commercial database "Rental Reports". Nevertheless, the Circuit found that matching of records across databases is precisely the sort of exercise It had previously held was sufficiently administrable to satisfy ascertainability, citing *Byrd*, 784 F.3d at 169–71 (*holding* ascertainability satisfied by the prospect of matching addresses from multiple as-of-yet unknown sources); *Hargrove v. Sleepy's LLC*, 974 F.3d 467, 480 (3d Cir. 2020) (*holding* ascertainability met by the prospect of cross-referencing a defendant's voluminous records with affidavits from putative class members); *City Select Auto Sales Inc. v. BMW of N. Am. Inc.*, 867 F.3d 434, 442 (3d Cir.2017) (same).

The Circuit stated that defendants were not able to defeat ascertainability simply because they had made a strategic decision to house records across multiple sources or databases in a way that made it difficult to match those records up. *RealPage,* 47 F.4th at 223.

The Circuit then questioned whether plaintiffs' burden included and actually required a file-by-file review to identify a mechanism or a calculus by which to ascertain the class. Even though the District Court apparently read into the Circuit's precedent a *per se* rule that a review of each individual file is not administratively feasible, the Circuit confirmed that is not the case and clarified Its own case law. *Id.*

The Third Circuit's findings in *Real Page* are discussed in more detail in the body of the opinion.

[18] The NDC consists of 11 digits, with each digit identifying a piece of information about the purchased drug, such as, drug manufacturer, specific strength, dosage form, and formulation of a drug, package size and type.

[19]Plaintiffs have not discussed specifically the Drug Name and National Drug Code (NDC) Reference Data as outlined in a U.S. government publication by the Health and Human Services Administration for the Center of Medicare Services (CMS), which is described in simple outline form at https://www.cms.gov/OpenPayments/Downloads/Drug-Name-and-NDC-Reference-Data-Instructions.pdf , last accessed 19 October 2022.

[20] See, e.g., Billing with National Drug Codes (NDCs) Frequently Asked Questions, Blue Cross Blue Shield of Illinois, March-April 2015, https://www.bcbsil.com/pdf/pharmacy/ndc_faqs.pdf, last accessed 19 October 2022 [guiding BCBS of Illinois contracted-with medical providers, such as hospitals and doctors' offices, on how to bill for prescription drugs]. *See also*, https://www.cms.gov/OpenPayments/Downloads/Drug-Name-and-NDC-Reference-Data-Instructions.pdf last accessed 19 October 2022.

[21] entities that create or help manage drug formularies for Health Care Insurers.

which informs on the Wholesalers' purchases from the mfrs and their sales to the Pharmacies.

Also, of singular importance are the following sets of data regarding filled prescriptions:

- Exponent data[22] provided by Iqvia, a leading publisher of pharmaceutical data in the United States;
- data from the Telecommunications Standards of the National Council for Prescription Drug Programs ("NCPDP");
-Transaction data from the PBMs and TPPs themselves,
- Records from databases useful for excluding federal and state government employees,

including data from Milliman, Inc., a premier global consulting and actuarial firm that collects data on health plans offered by states and local governments and collates it into Milliman Atlas of Public Employer Health Plans; and

- Data from Medicare and Medicaid.

Plaintiffs assert the transaction details of each drug purchase can be collated and tracked to a specific retailer, wholesaler, manufacturer and consumer, and that the entire transaction history for most if not all purchases of VCDs by putative ConEcoLoss class members is knowable by connecting the data from each player in the drug downstream. Linking these subsets of data archived by different defendants at various levels in the drug supply chain is how plaintiffs will provide "objective" data to identify putative class members in the ConEcoLoss class. Linking these data subsets, plaintiffs aver, can create an aggregate drug purchase history full of the necessary details of who purchased what VCDs and when as well as from where and from which manufacturer and wholesaler it was initially obtained.

The second prong, then, of the ascertainability test involves linking and matching the data from these various databases and software applications of various defendants at different levels of the drug supply chain to inform on the amounts paid for VCDs by the ConEcoLoss class members during the relevant period. The plaintiffs' enthusiasm for linking all these sets of data notwithstanding, the Court notes that neither the T3 data nor the Exponent data provide an obvious, tell-tale link between the purchasing consumer and the drug upstream players. To wit, there may be a considerable, and not entirely knowable, effort required to link disparate kinds of data, software applications, and processing systems to create a sufficient boundary condition that identifies relevant purchases and the class members who made them.

While this linking task appears formidable, the *RealPage* Court has nonetheless made clear that, if the data exist to reasonably identify class members, then having to link disparate kinds of data

[22] Iqvia's description of **Xponent** data: "Provides detailed prescriber level prescription information for the U.S., including dispensed drug prescription information from retail pharmacies (chain, mass merchandisers, independent, and food stores), mail service pharmacies, and long-term care facilities. It covers 93% of the retail channel and up to 77% coverage in the mail and LTC channels using a customized and patented projection methodology to generate accurate market estimates at a state, zip code or individual prescriber level." https://www.iqvia.com/insights/the-iqvia-institute/available-iqvia-data last accessed 19 Oct 2022.

to more accurately name all possible, putative members cannot be the reason to fail ascertainability. In *RealPage*, the Third Circuit found the records of putative class members were kept in two separate databases that used different software. Each database lacked a unique, or even a similar, identifier, for each putative class member, making it difficult to match records obtained from defendant's website with records obtained from Rental Reports, an external, nationwide database. This lack of unique identifier meant that, in order to detect a class member, plaintiffs would have to pore over each one of defendant's real estate records and try to determine what information there would readily match up that member in the national Rental Reports database. In other words, plaintiffs would have to slog through two unaligned databases iteratively back and forth to link defendants' real estate records to a National Real Estate database, in order to identify all class members. Nonetheless, the *RealPage* Court found that the matching of records was precisely the sort of exercise It had previously ruled to be feasibly administrable to satisfy ascertainability.

There were two reasons why the Third Circuit reversed the District Court's finding of no ascertainability. First, the Circuit found defendant's arguments that the class was not ascertainable depended on defendant's own conduct: to wit, that defendants had strategized to archive their own records complicatedly across multiple sources / databases, which resulted in an onerous burden in linking records to ascertain class members. *RealPage,* 47 F.4th at 223. Second, the Circuit found the District Court had misapplied the ascertainability standard by mistakenly wielding it as *per se* rule. The Third Circuit just said no and clarified what its precedents require. *Ibid.*

Reviewing its opinion in *Byrd,* 784 F.3d at 171, the Circuit cautioned that " 'the size of a potential class and the need to review individual files to identify its members are not reasons to deny class certification.' [*quoting Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 539–40 (6th Cir. 2012)]." *RealPage*, 47 F.4th at 224. As for its opinion in *Hargrove*, 974 F.3d at 470, 480, the Circuit said: "affidavits in combination with 'thousands of pages of contracts, driver rosters, security gate logs, and pay statements' sufficed to ascertain a class of full-time drivers for Sleepy's, despite gaps in the records and the work required to synthesize 'several distinct data sets.'." *RealPage*, 47 F.4th at 224. And, regarding its guidance in *City Select,* 867 F.3d at 441, the Circuit held " '[a]ffidavits, in combination with records or other reliable and administratively feasible means,' could satisfy [the] ascertainability standard", and had remanded to see "whether there were any gaps in a database not produced below that could make identifying putative class members inadministrable, *id.* at 442 & n.5." *RealPage*, 47 F.4th at 224.

Combining its rulings in *Byrd, Hargrove*, and *City Select,* the *RealPage* Circuit found that "a straightforward 'yes-or-no' review of existing records" was sufficient to show the administrative feasibility of identifying class members "even if [that] requires review of individual records with cross-referencing of voluminous data from multiple sources. *RealPage*, 47 F.4th at 224. "Indeed, the review

required here is even more straightforward than in *Byrd*, *Hargrove*, and *City Select*, as Appellants have already identified the records they require, demonstrated they are in [the defendants'] possession, and explained how those records can be used to verify putative subclass members." *Ibid.*

And, so have plaintiffs here done the same: they've identified the records they need, where they are located, and how to use them to verify subclass members. Thus, the takeaway from *RealPage* is that ascertainability for the ConEcoLoss class turns not on if the transaction records can or will "match" up, but on how these records can match up so that plaintiffs may determine with sufficient precision both the included ConEcoLoss class members, the excluded individual consumers, and the members in subclasses. It is beyond clear that administratively feasible data can come from many sources, in many forms or formats, and containing different fields manipulated by different software. As mentioned above, these data include transaction records from the Pharmacies, the PBMs' transaction records, the T3 data from the Wholesalers, the Iqvia Exponent external database data, the Milliman Atlas data, and data from Medicare and Medicaid, as well as records from other external databases. Plaintiffs' expert Laura Craft, PhD, provided in her Class Certification Report an example that certain of these data, particular from Pharmacies, can be matched to identify a set of ConEcoLoss putative class members.[23]

As the *RealPage* Court noted, plaintiffs need do no more at the class certification stage than identify with precision the records they need, show how to get and mine them to verify putative class and subclass members. Since that is the primary showing of administrative feasibility, plaintiffs have met their burden.

Accordingly, the Court finds this requirement met.

3.4 SUMMARY OF ConEcoLoss CLASS CERTIFICATION AND ConEcoLoss SUBCLASSES

In summary, the ConEcoLoss class has met both *Rule 23(a)* and *Rule 23(b)* requirements and the Court hereby certifies it with qualifications. That is, the Court has adopted a "hard test" of the accuracy of plaintiffs' 93 proposed subclasses presented in ECF No. 1747, Exhibit A. Using defendants' oppositions to (ECF Nos. 2008-7, Appendices F-7, G-8, H-9, I-10, J-11) to plaintiffs' subclasses, the Court reviewed the cited caselaw and researched other caselaw as needed to confirm the accuracy of plaintiffs' proposed subclasses. The "raw data" of the Court's research for the ConEcoLoss class and proposed subclasses is in Appendices 1-6. Therefore, the Court class certification of the ConEcoLoss class require plaintiffs to amend some of its proposed subclasses by incorporating the Court's recommendations in Table 3.

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[23] Expert Declaration of Laura R. Craft, PhD, Unredacted, Executed 10 Nov 2021, pp: 32 and 33.

The Court appreciates that plaintiffs may need to "match up" the recommendations in Table 3 and 4 to their proposed subclasses in both Economic Loss classes. ECF Docs. 1747 Exhibits A and B. This is because defendants' oppositions, upon which the Court relied, do not match up generally to plaintiffs' proposed subclasses. Rather they "cite check" the legal standards of each of the five claims in each proposed jurisdiction.

Table 3: For Plaintiffs' Five Claims, Summary of Incorrect Consumer Economic Loss Subclasses & Required Corrections to Proposed Subclasses

Breach of Express Warranty Subclass (EW) Group 1: Privity Not Required; PreSuit Notice Not Required	**Incorrectly Included States In Ps EW Group 1**	**Correct EW Group**
	FL: Privity not required; PreSuit notice required	MOVE to EW Group 2
	KY: Privity required; PreSuit notice not required	MOVE to EW Group 3
	RI: Privity not required; PreSuit notice required, but not much notice	MOVE to EW Group 2
	SC: Privity not required; PreSuit notice required	MOVE to EW Group 2
	WY: Privity not required; PreSuit notice required;	MOVE to EW Group 2
Breach of Express Warranty Subclass (EW) Group 2: Privity Not Required; PreSuit Notice May Be Required	**Incorrectly Included States In Ps EW Group 2**	**Correct EW Group**
		AL: Debatable if PreSuit notice is / may be required. Leaving in EW Group 2
		NY: Correct Group 3: NY does NOT require privity
		NC: Debatable if PreSuit notice is / may be required. Leaving in EW Group 2
	ND: Privity Required	MOVE to EW Group 3
		OR: Correct EW Group 3; PreSuit notice required
	TN: Privity & PreSuit Notice Required	**CREATE A NEW SUBCLASS/GROUPING FOR TN OR EXCLUDE TN FROM CLASS**
Breach of Express Warranty Subclass (EW) Group 3: PreSuit Notice Not Required; Privity May be Required	**Incorrectly Included States In Ps EW Group 3**	
	NONE	

Breach of Implied Warranty Subclass (IW) Group 1: Privity Not Required; PreSuit Notice Not Required	**Incorrectly Included States In Ps IW Group 1**	**Correct IW Group**
	HI: Defendants aver PreSuit notice required; Court disagrees	HI: in correct IW group 1
	IN: Defendants aver PreSuit notice required; Court disagrees	IN: in correct IW group 1. FDA recalls may suffice as pre-suit notice. Defendants cited a case about contractual duties, but here no contract between consumers & mfrs.
	MN: PreSuit notice required to some party in the drug supply chain	MOVE to IW Group 2
	MO: PreSuit notice required	MOVE to IW Group 2
	PA: Breach of Implied Warranty claim not permitted against drug mfr under PA law.	**REMOVE PA FROM ANY IW GROUP**
	SC: PreSuit notice required	MOVE to IW Group 2
Breach of Implied Warranty Subclass (IW) Group 2: Privity Not Required; PreSuit Notice Required	**Incorrectly Included States In Ps IW Group 2**	**Correct IW Group**
	NONE	
Breach of Implied Warranty Subclass (IW) Group 3: Privity Required; PreSuit Notice Not Required	**Incorrectly Included States In Ps IW Group 3**	**Correct IW Group**
	NY: Requires Privity & PreSuit notice for EcoLoss IW claims	MOVE to IW Group 4
Breach of Implied Warranty Subclass (IW) Group 4: Privity & PreSuit Notice Required	**Incorrectly Included States In Ps IW Group 4**	**Correct IW Group**
	NONE	

Fraud Subclass (FR) Group 1: Recklessness	Incorrectly Included States In Ps FR Group 1	Correct FR Group
	AK: Defendants aver Knowledge of falsity of statement required	MOVE to FR Group 3
	OH: Requires either Knowledge, or Recklessness, which amounts to inferred Knowledge	MOVE to FR Group 3
	MA: Defendants aver Knowledge of falsity of statement required	MOVE to FR Group 3
	NC: Requires Scienter, intent to deceive	MOVE to FR Group 3
	SD: Requires either Knowledge or Recklessness	MOVE to FR Group 3
Fraud Subclass (FR) Group 2: Ignorance of Truth	Incorrectly Included States In Ps FR Group 2	Correct FR Group
	AR: requires Knowledge of the falsity	MOVE to FR Group 3
	ID: requires Knowledge of the falsity	MOVE to FR Group 3
	MN: requires Knowledge of the falsity	MOVE to FR Group 3
	TN: requires Recklessness	MOVE to FR Group 1
Fraud Subclass (FR) Group 3: Knowledge of Falsity	Incorrectly Included States In Ps FR Group 3	Correct FR Group
	NONE	

Consumer Protection Subclass (CP) Group 1: No Intent, Standardized Violation Language, And No Pre-Suit Notice	Incorrectly Included States In Ps CP Group 1	Correct CP Group
	IL: Requires Intent	MOVE to CP Group 4
	SC: class action claim under ConProtAct not permitted	**REMOVE SC FROM ANY CP GROUP**
	TN: class action claim under ConProtAct not permitted	**REMOVE TN FROM ANY CP GROUP**
	WV: suits for drug purchases under WV Consumer Protection Act not permitted	**REMOVE WV FROM ANY CP GROUP**
Consumer Protection Subclass (CP) Group 2: No Intent, Non-Standardized Violation Language And No Pre-Suit Notice	Incorrectly Included States In Ps CP Group 2	Correct CP Group
	KS: Intent Required	MOVE to CP Group 4
Consumer Protection Subclass (CP) Group 3: No Intent, Standardized Violation Language BUT Require PreSuit Notice	Incorrectly Included States In Ps CP Group 3	Correct CP Group
	AL: class action claim under ConProtAct not permitted	**REMOVE AL FROM ANY CP GROUP**
	GA: class action claim under ConProtAct not permitted	**REMOVE GA FROM ANY CP GROUP**
	MS: class action claim under ConProtAct not permitted	**REMOVE MS FROM ANY CP GROUP**
Consumer Protection Subclass (CP) Group 4: Requires Intent, Use Standardized Violation Language, PreSuit Notice Not Required	Incorrectly Included States In Ps CP Group 4	Correct CP Group

	AR: class action under ConProtAct not allowed	**REMOVE AR FROM ANY CP GROUP**
Consumer Protection Subclass (CP) Group 5: Requires Intent, Use Standardized Violation Language, PreSuit Notice Not Required	**Incorrectly Included States In Ps CP Group 4**	**Correct CP Group**
	NONE	

Wholesaler Unjust Enrichment Subclass (WHUE) Group 1: Higher Burden, UE = Primary Claim, Direct Benefit Required	**Incorrectly Included States In Ps WHUE Grp 1**	**Correct UE Group**
Plaintiffs list: only Texas in this Group; Defendants do not include Texas in opposition	NONE	
Wholesaler Unjust Enrichment Subclass (WHUE) Group 2: Higher Burden; UE= Alternative Claim; Direct Benefit Not Required	**Incorrectly Included States In Ps WHUE Grp 2**	**Correct UE Group**
Plaintiffs list: Alabama, Montana in this Group; Defendants do not include Montana in opposition	NONE	

Wholesaler Unjust Enrichment Subclass (WHUE) Group 3: Normal Burden; UE= Alternative Claim; Direct Benefit Not Required	**Incorrectly Included States In Ps WHUE Grp 3**	**Correct UE Group**
Plaintiffs list: Arizona, Arkansas, Connecticut, Maryland, Minnesota, Rhode Island, Vermont, Wyoming	CT: requires Higher burden	MOVE to WHUE Group 2
Wholesaler Unjust Enrichment Subclass (WHUE) Group 4: Normal Burden; UE= Alternative Claim;	**Incorrectly Included States In Ps WHUE Grp 4**	**Correct UE Group**

Direct Benefit Required		
Plaintiffs list: Alaska, Delaware, Florida, Georgia, Idaho, Nebraska, New Jersey, North Dakota, Ohio, Pennsylvania, Virginia, Washington	DE: requires Higher burden FL: requires Higher burden GA: Direct Benefit not required, not changing Plaintiffs' choice OH: requires Higher burden	MOVE to WHUE Group 6 MOVE to WHUE Group 6 MOVE to WHUE Group 6
Wholesaler Unjust Enrichment Subclass (WHUE) Group 5: Normal Burden; UE = Alternative Claim; Direct Benefit Required	**Incorrectly Included States In Ps WHUE Grp 5**	
Ps list: California, Colorado, DC, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Massachusetts, Mississippi, Missouri, Nevada, New Mexico, New York, North Carolina, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Utah, Puerto Rico	CA: May require Higher burden CO: requires Higher burden IN: requires Higher burden	MOVE to WHUE Group 6 MOVE to WHUE Group 6 MOVE to WHUE Group 6
Wholesaler Unjust Enrichment Subclass (WHUE) Group 6: Heightened Burden, UE = Alternative Claim, Direct Benefit Req'd	**Incorrectly Included States In Ps WHUE Group 6**	**Correct UE Group**
Ps List: Only Kentucky		*See* above: **MOVE DE, FL, OH, CA, CO, IN to this Group**

4.0 THIRD PARTY PAYOR ECONOMIC LOSS CLASS CERTIFICATION

4.1 CLASS DEFINITION AND ALIGNMENT WITH CONSUMER ECOLOSS CLASS

Plaintiffs seek a class, identified herein as TPPEcoLoss, of all Third-Party Payors[24] that, from at least January 1, 2012 through the date of final recall as of November 10, 2021, paid partly or entirely for a valsartan-containing drug sold in the U.S. that was manufactured, distributed, or sold by any API or FD Manufacturer, Wholesaler, or Pharmacy defendant herein. Put differently, the putative TPPEcoLoss class members here include those insurers who paid for / reimbursed the ConEcoLoss members for their VCDs according to the health care insurance policy of the ConEcoLoss member (if such policy was in play). As for general damages incurred by the TPPEcoLoss class members, plaintiffs again assert the VCDs were worthless because, had the contamination been publicly known, VCDs would not have been sold, i.e., were not merchantable. TPP plaintiffs seek as their economic loss the full cost of their payments for their insured's VCDs over the relevant period.

Plaintiffs allege the economic losses of both putative classes, consumers and TPPs are aligned. As used herein, such alignment means both Economic Loss classes share two factors: both allege a parallel cause for their economic loss; and the total loss of both Economic Loss classes is the sum of the loss of each.[25] Since consumers and their TPPs typically pay for that portion of the drug cost which the other party does not, the Court finds it straightforward to consider the legal interests and claims as well as the economic losses of both classes aligned. However, even though the economic loss of each class is a mirror image of the other, alignment of the TPPEcoLoss class with the ConEcoLoss class does not preclude a thorough review of *Rule 23* requirements for the proposed TPPEcoLoss class.

Plaintiffs propose to partition the TPPEcoLoss class into 19 subclasses[26] based on their interpretation of state law standards for the same legal claims asserted against consumers: breach of express warranty, breach of implied warranties of merchantability and fitness, fraud, violation of state consumer protection acts, and unjust enrichment. For all subclasses, the relevant time duration is from at least 1 January 2012 through the date of final recall as of 10 November 2021. .

For an exposition of *Rule 23* legal standards, *see supra* Sections 3.2 and 3.3. We apply these standards in our review here of the proposed TPPEcoLoss class, and in Section 5.0 of the proposed Medical Monitoring Classes.

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[24] Third Party Payors ["TPPs"] provide health care benefits for consumers and may be an employer's insurance company or a health and welfare plan providing health care benefit to employees or beneficiaries. TPPs serve as health care insurers. TPPs have paid in whole or in part, or reimbursed consumers, for the VCDs at issue in this case.

[25] *See In re EpiPen Marketing, Sales Practices and Antitrust Litigation*, MDL 2785, 2020 WL 1873989 (D. Kan. 7 Feb 2020) [*exemplifying* such alignment of consumers' and TPPs' interest in recovering economic loss for overpayment of a pharmaceutical that did not warrant the cost.

[26] *See* ECF No. 1747 Exhibit B, plaintiffs' listing of TPPEcoLoss subclasses, also called herein groupings.

4.2 *RULE 23(a)* REQUIREMENTS

4.2.1 TPPEcoLoss Class: *Rule 23 (a)(1)* - Numerosity

Based on the alignment between TPPs and their insureds who purchased VCDs, plaintiffs estimate a very large number of TPPs are putative members in this class as there are thousands of TPPs nationwide who could have served the possible millions of members in the ConEcoLoss class. Deducing that a large number of ConEcoLoss class members dictates a comparatively large number of TPPEcoLoss members, plaintiffs aver there's a high probability of at least 40 TPPs in this class. Even though this deduction lacks a demonstrated preponderance of the evidence, the Court finds it plausible and reasonable, and, accordingly, finds this requirement is met.

4.2.2 TPPEcoLoss Class: *Rule 23(a)(2)* - Commonality

Plaintiffs allege the economic loss to consumers and their TPPs arises in the same way. Consumers and TPPs paid (either in full or in part) for their VCDs because of defendants' breach of warranty of drug safety, fraud, omission of their non-compliance with cGMPs, and resultant unjust enrichment. Plaintiffs aver there is a single common issue in both economic loss classes—payment for VCDs they regard as having zero economic value compared to uncontaminated valsartan—for which defendants must pay back. Plaintiffs also aver the facts resolving their legal claims center on defendants' non-compliance with the FDAs cGMPs that resulted in nitrosamine contamination of valsartan API and finished doses.

As in their arguments relating to the ConEcoLoss class, defendants aver that the wide variability relating to the ingested VCDs in terms of NDC, dosage, duration, and recall dates attest to a lack of common facts that negate commonality as to the economic loss. Plaintiffs counter that this variability to no great extent affects the commonality of cause, i.e., defendants' conduct that resulted in VCD contamination, which, they aver, girds the entire litigation.

The ultimate factual / legal issues for TPPEcoLoss class certification are:
- whether the TPPEcoLoss class members paid in whole or in part for their insureds' VCD prescriptions, regardless of the variability in the prescription specifics;
- whether paid-for / reimbursed VCD prescriptions were contaminated according to FDA recalls; and
- whether, and to what extent, the VCDs, because of their contamination, were worth less than the price paid for / reimbursed by the TPPEcoLoss class members.[27]

[27] The Court appreciates the very large disagreement between the parties as to the economic value of the contaminated VCDs, which runs as a theme through the class certification arguments, especially, those relating to damages, and the class expert reports. This disagreement boils down to: **Plaintiffs' argument:** if the contamination were known from the beginning, the VCDs would not have been sold and are therefore economically worthless. Economic loss damages amount to the full cost paid for the VCDs.

As these facts and issues are common, pertinent, and central to the entire TPPEcoLoss class and implicate each of the five asserted claims, the Court finds this requirement met.

4.2.3 TPPEcoLoss Class: *Rule 23 (a)(3)* – Typicality

Plaintiffs have proposed two TPPEcoLoss Class Representatives, MSP Recovery Claims, Series LLC ["MSPRC"] and Maine Automobile Dealers Association, Inc. Insurance Trust ("MADA"). These seek economic loss damages through the 5 legal claims on behalf of the unnamed, putative TPP members.

As noted above, the commonality and typicality requirements tend to merge. Even if there are fact differences between named and unnamed TPPs, such as to their insureds, the amount of insurance coverage for the VCDs, the VCDs covered in the TPP's formulary, etc., these specifics do not raise a conflict between the named class representatives and the rest of the putative class. All class members share key issues of law as well as the key fact: they allege their economic loss arises from same or substantially similar conduct by defendants, which resulted in VCD contamination. Such a lack of conflict in the legal claims and interests between the named and the unnamed class members is the hallmark of typicality. Accordingly, the Court finds this requirement met.

4.2.4 TPPEcoLoss Class: *Rule 23 (a) (4)* - Adequacy

As discussed above for the ConEcoLoss class, this requirement looks to whether there is a conflict of interest between the named and unnamed plaintiffs. The Court's goal is to make sure the facts and legal issues pertinent to the class representatives do not unfairly play down those of the unnamed plaintiffs.

The TPP plaintiffs allege that named and unnamed TPPEcoLoss plaintiffs have experienced the same kind of economic loss. And, had they known of the VCD contamination, they would not have paid or reimbursed for these drugs because they were not merchantable. There is no fundamental, or even tangential, conflict between the allegations of economic loss by the named representatives and those by the unnamed class members; every TPPEcoLoss plaintiff asserts the same legal claims regarding their economic loss, and seeks the same kind of relief. Moreover, all TPPEcoLoss plaintiffs assert the same basic cause for their economic loss: defendants' violation of cGMPs, which introduced genotoxic

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Defendants' argument: the NDMA/NDEA contamination notwithstanding, the VCDs provided consumers the therapeutic value of lowering their blood pressure as expected, which value must be considered to calculate properly the economic worth of the VCDs at issue. Subtracting the therapeutic value from the full cost paid for the VCDs yields such a proper calculation.

This disagreement points straight to a central trial issue: what economic loss damages do defendants owe plaintiffs? In resolving predominance and ascertainability requirements, the Court has declined to adopt either party's theory of damages. Rather, the Court acknowledges that "some" economic value may be owed plaintiffs, which preserves both the precise calculus of damages and the resolution of the 5 legal claims of loss for the factfinder. The Court more fully discusses this dispute in section 6.0 relating to the reports of the class certification experts.

contaminants into valsartan API and finished doses.

The claims for economic loss of each TPPEcoLoss class member certainly has facts unique to it, such as, the prescribed VCD of their insured consumer, the insureds' prescription dosages and durations, the total amounts of economic loss, differences in state law standards across the five asserted claims, etc. But the uniqueness of these facts and state law standards do not support a theory of actual or potential conflict between the named and unnamed plaintiffs. The alleged reason for the TPP economic loss does not vary from one TPPEcoLoss plaintiff to another. In addition, TPPEcoLoss plaintiffs have retained counsel who are experienced in MDL litigation and class certification disputes. These are Gregory Hansel of Preti Flaherty Beliveau & Pachios, Chartered, LLP, Counsel for MADA[28]; and Jorge Mestre of Rivero Mestre LLP, Counsel for MSPRC.[29] Accordingly, the Court finds this requirement met.

4.3 *RULE 23(b)(3)* REQUIREMENTS

4.3.1 TPPEcoLoss Class: Predominance

Plaintiffs list their proposed 19TPPEcoLoss subclasses in ECF Doc. 1747-2, Exh. 2, and aver these correspond to specific variations in state law standards for each claim and therefore control for differences in facts and law among all putative TPPEcoLoss members. Plaintiffs argue that critical, common issues dominate the economic loss of each putative TPPEcoLoss member over any individualized specifics, especially, divergent state law standards of economic injury for any of the five asserted claims. As plaintiffs aver, these central issues revolve around defendants' conduct of asserting that the VCDs were the chemical equivalent of the patented reference listed drug [RFL] in the Orange Book.

Specifically, these issues are:

- whether, by presenting consumers with an FDA-approved VCD label, the defendant mfrs made express warranties to TPPs of the "sameness" of their products to the VCDs' RLDs, which implied the VCDs were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels, to wit, the VCDs were neither contaminated, adulterated, nor misbranded;
- whether additional information from defendant mfrs' websites and other of mfrs' published information reinforced these alleged warranties that the VCDs complied with cGMPs and did not, and were unlikely to, contain any ingredients, including genotoxins such as nitrosamines, not in the RLD

[28] Mr. Handel is currently co-lead counsel for direct purchasers in an ongoing MDL *In re Automotive Parts Antitrust Litigation*, MDL No. 2311 and served as co-lead counsel in *Marine Hose Antitrust Litigation*, MDL No. 1888 (S.D. Fla.), now terminated, where there was a settlement for a class of purchasers.

[29] Mr. Mestre is interim co-lead counsel for the putative class of third party payors in the consolidated class action, *In re Metformin Marketing and Sales Practices Litigation* (20-cv-2324, D.N.J., Arleo, J.)

Orange book listing;
- whether, in constructing their drug formularies, TPPs, their PBMs, and other agents so involved reasonably relied on the VCD labels that these drugs were legally compliant in terms of pharmaceutical equivalence, safety, etc. and were otherwise the same as their RLD counterparts, which induced TPP plaintiffs to include the VCDs in their drug formularies.

At heart, plaintiffs argue that whether defendants made representations and express warranties to the TPPs that their VCDs were the same as the RLD is a matter of class-wide, not individualized, proof for each TPP.

Defendants dispute plaintiffs' assertion that the VCD labels imposed an express or implicit warranty of mfrs' cGMP compliance because the offer for sale of a generic prescription drug in the U.S. marketplace does not act as a warranty of its exact chemical identity to the Orange Book RLD composition. They state the VCDs were pharmaceutically and biologically equivalent to the RLD. Defendants also aver the VCDs marketed to TPPs and consumers were consistent with other characteristics of the RLD: its chemical and biological efficacy, and therefore its quality, purity, identity and strength as well. Further, defendants argue there are so many variations in state law standards, e.g., privity for a breach of warranty and correct intent in a fraud claim, which necessitates the marshalling of individualized facts for each TPP.

As for the ConEcoLoss Class, the Court has researched the correctness of the state law standards that plaintiffs advance and upon which plaintiffs base their TPPEcoLoss subclasses. The Court views its "legal cite-checking" initiative as a key pathway to confirm that predominance has been deconstructed properly, leaving only those TPPEcoLoss subclasses that have substantially similar fact and law issues that dominate throughout.

Again, as with the ConEcoLoss subclasses, the Court worked from defendants' opposition chart of state law jurisprudence to research and confirm the legal correctness of plaintiffs' proposed subclasses (which is the same as for the ConEcoLoss groupings). The Court's findings in Table 4 in Section 4.4 *infra* prevail here as plaintiffs' 19 TPPEcoLoss subclasses. Accordingly, the Court finds this requirement met.

4.3.2 TPPEcoLoss Class: *Rule 23(b)3* - Superiority

The discussion in Section 3.3.2 regarding this requirement applies equally here. Plaintiffs aver the singular cause of their economic loss is defendants' conduct, comprehensively sued for in the 5 legal claims to thereby determine the full economic loss of the entire class. Plaintiffs assert this singularity of cause and set of legal issues for all putative class members is why a class action is the superior litigation mechanism. Defendants do not address directly this alleged cause but focus on the variability in state

law standards for plaintiffs' claims. Again, as asserted above, having been the transferee court of this MDL since consolidation four years ago, the Court sees little intelligent rationale for not concentrating litigation efforts and resolving all TPPEcoLoss claims here through a class action in which subclasses have been divvied up according to the variability in the required elements of the state law claims.

Managing a TPPEcoLoss class with 18 subclasses is likely less onerous than managing the 93 subclasses of the ConEcoLoss class. Weighing this burden against its own experience with the MDL, the Court observes that certification of a large TPPEcoLoss class and a proper division of it into subclasses based on state law variation in legal standards is the better mechanism for efficient adjudication than individual law suits by TPPEcoLoss plaintiffs. Class certification with appropriately defined subclasses promotes fewer inconsistent verdicts and concentrates litigation efforts for both parties into fewer trials as well as promoting Class Action settlement, thereby decreasing unnecessary cost and effort overall for both parties. Accordingly, the Court finds this requirement met.

4.3.3 TPPEcoLoss Class: *Rule 23(b)(3)* - Ascertainability

As the Third Circuit has taught: what is not required to comply with this requirement is that plaintiffs have to "identify the class members at class certification stage." *Hargrove v. Sleepy*, 974 F.3d 467, 479 (3d Cir. 2020). What is required at this stage is "that Appellants show there is a 'reliable and administratively feasible mechanism,' *Byrd [v. Aaron's, Inc.]*, 784 F.3d [154] at 163 [3d.Cir 2015] (*quoting Carrera [v. Bayer Corp.]*, 727 F.3d [300] at 306) [3rd Cir. 2013]." *Ibid.*

Compared to the parties' disputed methods for calculating the actual economic losses of both Economic Loss classes—and in particular how to factor in offsets for VCD costs from Medicare, Medicaid, or drug discounters, such as Good Rx—determining what TPPs are actually in the TPPEcoLoss class is relatively simple. Plus, it appears relatively uncomplicated for plaintiffs to have arrived at a methodology that identifies a definitive list of TPPs who paid for U.S. prescriptions during the relevant time period. Most of these data are available from the records of the TPPs or their agents who managed TPP drug reimbursements, and/or from the Pharmacies, and/or from the Pharmacy Benefit Managers ["PBMs"] who worked with the TPPs and/or their PBM agents, all of which worked individually or separately to establish drug formularies and reimbursement calculi. Such formularies coupled with Pharmacy records of VCD transactions coupled with Iqvia data (discussed *supra*) go a considerable way in developing a reliably and reasonably objective methodology of ascertaining TPPEcoLoss class members. Moreover, both plaintiffs' and defendants' expert reports inform on the quantity and quality of the data needed to ascertain members definitively as well as the pathway for doing so. While not agreeing as to what data pinpoint "perfect" TPPEcoLoss class membership, both parties' experts generally do confirm the data mentioned above are relevant, objective, and useful in creating a feasible, if imperfect, method of ascertaining class membership. As feasible, and not perfect,

ascertainability is the standard, the Court finds this requirement met.

4.4 SUMMARY OF TPPEcoLoss CLASS CERTIFICATION AND TPPEcoLoss SUBCLASSES

In summary, the TPPEcoLoss class has met both Rule 23(a) and Rule 23(b) requirements. Table 4 below sets forth the results of the Court's "cite checking" of the legal standards in each jurisdiction for plaintiffs' proposed TPPEcoLoss subclasses and amends these accordingly. The Court hereby certifies the TPPEcoLoss class and requires plaintiffs to amend their 19 TPP subclasses according to Table 4, while again appreciating that plaintiffs may need to "match up" the recommendations in Table 4 to their proposed TPPEcoLoss subclasses.

Table 4: For Plaintiffs' Five Claims, Summary of Incorrect TPP Economic Loss Subclasses & Required Corrections to Proposed Subclasses

Breach of Express Warranty Subclass (EW) Group a: Privity Not Required; PreSuit Notice Not Required	**Incorrectly Included States In Ps EW Group a**	**Correct EW Group**
	FL: Privity not required; PreSuit notice required	MOVE to EW Group b
	KY: Privity required; PreSuit notice not required	MOVE to EW Group c
	RI: Privity not required; PreSuit notice required, but not much	MOVE to EW Group b
	SC: Privity not required; PreSuit notice required	MOVE to EW Group b
	WY: Privity not required; PreSuit Notice required	MOVE to EW Group b
Breach of Express Warranty Subclass (EW) Group b: Privity Not Required; PreSuit Notice May Be Required	**Incorrectly Included States In Ps EW Group b**	**Correct EW Group**
		AL: Debatable if PreSuit notice is or may be required; leaving in EW Group b
		NY: in correct EW Group b; does NOT require privity
		NC: Debatable if PreSuit notice is or may be required; leaving in EW Group b
	ND: Privity required	MOVE to EW Group c
		OR: in correct EW Group b; PreSuit notice required
	TN: Privity & PreSuit Notice Required	**CREATE NEW EW SUBCLASS/GROUPING FOR TN OR EXCLUDE TN FROM CLASS**
Breach of Express Warranty Subclass (EW) Group c: PreSuit Notice Not Required; Privity May be Required	**Incorrectly Included States In Ps EW Group c**	
	NONE	

Breach of Implied Warranty Subclass (IW) Group a: **Privity Not Required; PreSuit Notice Not Required**	Incorrectly Included States In Ps IW Group a	Correct IW Group
	HI: Defendants aver PreSuit notice required; Court disagrees	HI: In correct group IW a
	IN: Defendants aver PreSuit notice required; Court disagrees	IN: in correct group IW a. FDA recalls may suffice as PreSuit notice. Defendants' cited case concerns contractual duties; but no contract here. .
	MN: PreSuit notice required to a party in supply chain	MOVE to IW Group b
	MO: PreSuit notice required	MOVE to IW Group b
	PA: Breach of Implied Warranty claim not permitted against drug mfr under PA law	**REMOVE PA FROM ANY IW GROUP**
	SC: PreSuit notice required	MOVE to IW Group b
Breach of Implied Warranty Subclass (IW) Group b: **Privity Not Required; PreSuit Notice Required**	Incorrectly Included States In Ps IW Group b	Correct IW Group
	NONE	
Breach of Implied Warranty Subclass (IW) Group c: **Privity Required; PreSuit Notice Not Required**	Incorrectly Included States In Ps IW Group c	Correct IW Group
	NY: Privity and PreSuit notice required in EcoLoss IW claim	MOVE to IW Group 4

Breach of Implied Warranty Subclass (IW) Group d: **Privity Required; PreSuit Notice Required**	Incorrectly Included States In Ps IW Group d	Correct IW Group
	NONE	

Fraud Subclass (FR) Group a: **Recklessness**	Incorrectly Included States In Ps FR Group a	Correct FR Group
	AK: Defendants aver Knowledge of falsity of statement required	MOVE to FR Group c
	OH: Requires either Knowledge, or Recklessness, which amounts to inferred Knowledge	MOVE to FR Group c
	MA: Defendants aver knowledge of falsity of statement required	MOVE to FR Group c
	NC: Requires Scienter, intent to deceive	MOVE to FR Group c
	SD: Requires either Knowledge or Recklessness	MOVE to FR Group c
Fraud Subclass (FR) Group b: **Ignorance of the Truth**	Incorrectly Included States In Ps FR Group b	Correct FR Group
	AR: requires Knowledge of the falsity	MOVE to FR Group c
	ID: requires Knowledge of the falsity	MOVE to FR Group c
	MN: requires Knowledge of the falsity	MOVE to FR Group c
	TN: requires Recklessness	MOVE to FR group a
Fraud Subclass (FR) Group c: **Knowledge**	Incorrectly Included States In Ps FR Group 3	Correct FR Group
	NONE	

Consumer Protection Subclass (CP) Group a: Intent Not Required; Standardized Violation Language; PreSuit Notice Not Required	**Incorrectly Included States In Ps CP Group a**	**Correct CP Group**
	IL: Requires Intent	MOVE to CP Group d
	SC: class action claim under ConProtAct not permitted	**REMOVE SC FROM ANY CP GROUP**
	SC: class action claim under ConProtAct not permitted	**REMOVE TN FROM ANY CP GROUP**
	WV: suits for drug purchases under WV Consumer Protection Act not permitted	**REMOVE WV FROM ANY CP GROUP**
Consumer Protection Subclass (CP) Group b: Intent Not Required; Non-Standardized Violation Language; PreSuit Notice Not Required	**Incorrectly Included States In Ps CP Group b**	**Correct CP Group**
	KS: Intent Required	MOVE to CP Group d
Consumer Protection Subclass (CP) Group c: Intent Not Required; Standardized Violation Language; PreSuit Notice Required	**Incorrectly Included States In Ps CP Group c**	**Correct CP Group**
	AL: class action claim under ConProtAct not permitted	**REMOVE AL FROM ANY CP GROUP**
	GA: class action claim under ConProtAct not permitted	**REMOVE GA FROM ANY CP GROUP**
	MS: class action claim under ConProtAct not permitted	**REMOVE MS FROM ANY CP GROUP**
Consumer Protection Subclass (CP) Group d: Intent Required; Standardized Violation Language; PreSuit Notice Not Required	**Incorrectly Included States In Ps CP Group d**	**Correct CP Group**
	AR: class action claim under ConProtAct not permitted	**REMOVE AR FROM ANY CP GROUP**

Wholesaler Unjust Enrichment Subclass (WHUE) Group a: **Higher Burden; UE = Primary Claim; Direct Benefit Required**	Incorrectly Included States In Ps WHUE Group a	Correct UE Group
Plaintiffs list: only Texas in this Group; Defendants do not include Texas in their opposition	NONE	
Wholesaler Unjust Enrichment Subclass (WHUE) Group b: **Higher Burden; UE= Alternative Claim; Direct Benefit NOT Required**	Incorrectly Included States In Ps WHUE Group b	Correct UE Group
Plaintiffs list: only Alabama, Montana in this Group; Defendants do not include Montana in their opposition	NONE	
Wholesaler Unjust Enrichment Subclass (WHUE) Group c: **Normal Burden; UE= Alternative Claim; Direct Benefit NOT Required**	Incorrectly Included States In Ps WHUE Group c	Correct UE Group
Plaintiffs list: Arizona, Arkansas, Connecticut, Maryland, Minnesota, Rhode Island, Vermont, Wyoming	CT: Higher burden required	MOVE to WHUE Group b
Wholesaler Unjust Enrichment Subclass (WHUE) Group d: **Normal Burden; UE= Alternative Claim; Direct Benefit Required**	Incorrectly Included States In Ps WHUE Group d	Correct UE Group
Plaintiffs list: Alaska, Delaware, Florida, Georgia, Idaho, Nebraska, New Jersey, North Dakota, Ohio, Pennsylvania, Virginia, Washington	DE: Higher burden required FL: Higher burden required GA: Direct Benefit not required, but not changing Plaintiffs choice OH: Higher burden required	MOVE to WHUE Group f MOVE to WHUE Group f MOVE to WHUE Group f

Wholesaler Unjust Enrichment Subclass (WHUE) Group e: Normal Burden, UE = Alternative Claim, Direct Benefit Required	**Incorrectly Included States In Ps WHUE Group e**	
Plaintiffs list: California, Colorado, DC, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Massachusetts, Mississippi, Missouri, Nevada, New Mexico, New York, North Carolina, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Utah, Puerto Rico	CA: Higher burden may be required CO: Higher burden required IN: Higher burden required	MOVE to WHUE Group f MOVE to WHUE Group f MOVE to WHUE Group f
Wholesaler Unjust Enrichment Subclass (WHUE) Group 6: Heightened Burden; UE = Alternative Claim; Direct Benefit Required	**Incorrectly Included States In Ps WHUE Group 6**	**Correct UE Group**
Plaintiffs List: Only Kentucky		***See* above: Move DE, FL, OH, CA, CO, IN to this Group**

5.0 MEDICAL MONITORING CLASS CERTIFICATION

5.1 CLASS DEFINITIONS

Plaintiffs seek certification of three medical monitoring ["MedMon"] classes against all defendants—Mfrs, Wholesalers, and Pharmacies. Two classes pursue medical monitoring as a legal claim independent of any other accompanying claim; these are termed generally IND MedMon classes. One IND MedMon class is sought under *Rule 23(b)(3)* and termed *23(b)(3)* IND MedMon class. The other independent class is sought as an alternative under *Rule 23(b)(2)* and termed *23(b)(2)* IND MedMon class. Plaintiffs also seek a single class under *Rule 23(b)(2)* that pursues medical monitoring as a remedy for an accompanying legal claim, and is termed *23(b)(2)* REM MedMon class.

Medical monitoring involves payment for diagnostic testing and medical checkups of individual class members to detect and diagnose certain cancers as early as possible. Relying on medical literature that associates NDMA/NDEA ingestion with an increased risk of cancer incidence, plaintiffs have alleged MedMon class members are more likely to develop certain cancers because of their ingestion during the relevant period of nitrosamines presumed present in their prescribed VCDs. Such cancers may not manifest until after a latency period or never manifest.

To enter any of the proposed MedMon classes, an individual must meet the following boundary condition: that is, they must have consumed a Lifetime Cumulative Threshold ["LCT"] of NDMA, NDEA, or both, from their prescribed VCDs sold in the U.S. during the relevant period. Simply, the Lifetime Cumulative Threshold is a number calculated from an individual's ingestion history of VCDs.

Table 5 shows the various calculations of LCT, depending on what APIs were ingested, for how long, and at what dosage. Of note, the LCT is a lower limit number, that is, a minimum threshold number calculated from the particular VCD(s) ingested, dosage(s), and duration of ingestion. A calculation equal to or above an LCT in Table 5 places the individual into one of the MedMon Classes depending on the medical monitoring relief sought and if the state law of their domicile so permits.

Table 5: LCT Calculation from VCD API, dosage, and duration for any MedMon Class Member

Daily Dosage	Duration	VCD Active Pharmaceutical Ingredient ["API"]
320 mg	3 months	Zhejiang Huahai API
	18 months	Hetero API
	54 Months	API from: Mylan OR Aurobindo OR Combination of Mylan and Aurobindo
160 mg	6 months	Zhejiang Huahai API
	32 months	Hetero API
	108 mos (9 yrs)	API from: Mylan OR Aurobindo OR Combination of Mylan and Aurobindo
80 mg	12 months	Zhejiang Huahai API
	64 months	Hetero API
	216 months	API from: Mylan OR Aurobindo OR Combination of Mylan and Aurobindo
40 mg	24 months	Zhejiang Huahai API
	128 months	Hetero API
	432 months	API from: Mylan OR Aurobindo OR Combination of Mylan and Aurobindo

5.1.1 The *Rule 23(b)(3) or (b)(2)* IND MedMon Class Definition

Asserted in the alternative under either *Rule 23(b)(3)* or *(b)(2)*, the IND MedMon classes include those who ingested an LCT of NDMA and/or NDEA from contaminated VCDs and who reside in U.S. jurisdictions where the law permits medical monitoring as a legal claim independent of any other pleaded in the litigation. Both proposed IND MedMon classes, under either *Rule 23(b)(3)* or alternatively*23(b)(2),* includes relevant individuals residing in Alaska, Arizona, Colorado, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Maine, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, West Virginia, Wyoming.

Excluded jurisdictions for both IND MedMon classes are: Alabama, Arkansas, California, Connecticut, Georgia, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Mississippi, Nebraska, New Jersey, Ohio, Oklahoma, South Carolina, Tennessee, Texas, Virginia, Washington, and Wisconsin.

5.1.2 The *Rule 23(b)(2)* REM MedMon Class Definition

Asserted under *Rule 23(b)(2)*, the REM MedMon class includes those individuals who have

ingested during the relevant period an LCT of NDMA and/or NDEA from prescribed VCDs and who also reside in U.S. jurisdictions where the law permits medical monitoring only as a remedy to a pleaded claim. This class specifically includes those relevant individuals residing in every U.S. jurisdiction, except Mississippi.

5.2 PARTIES' CONTENTIONS

For class certification of the IND MedMon Class under either *Rule 23(b)(2) or (b)(3)*, plaintiffs assert that their submission of persuasive authority on how states' courts have or would rule on medical monitoring should aid this Court's certification analysis. Alternatively, plaintiffs suggest that if a state court ruling on medical monitoring is unclear or absent, the Court may divide either the *23(b)(3)* or the *23(b)(2)* IND MedMon Class into two: one for states where medical monitoring is an independent claim not requiring proof of present injury; and the other for those states where medical monitoring is an independent claim but with ancillary requisites.[30] Defendants contend that, for this class, the law in several jurisdictions is undecided as to whether medical monitoring is an independent cause of action, which militates against class certification.

For class certification of the REM MedMon class, plaintiffs likewise suggest that, if unsatisfied with the accuracy of its submission on state law requirements, the Court may divide this class into two: one class of those jurisdictions that both prohibit medical monitoring as an independent claim and requiring no present physical injury or only a showing of sub-cellular injury; and the other class of those other jurisdictions that prohibit medical monitoring as an independent claim. Defendants assert several states lack judicial precedent on whether medical monitoring is a remedy, including Tennessee, Connecticut, Delaware, Indiana, Georgia, and Nebraska and question the accuracy of plaintiffs' persuasive authority. Plaintiffs respond that, for any proposed MedMon class, the lack of jurisprudential clarity from the highest state court does not act against either the independence of the remedy or the availability of a medical monitoring legal claim. They aver that, even in the absence of a ruling by a state's highest court, an adjudicating court can, and should, predict how the highest state court would rule in order to provide needed jurisprudence[31] and resolve any ambiguity as to medical monitoring.

Generally, plaintiffs assert that both proposed *Rule 23(b)(2)* IND and REM MedMon classes as well as the *Rule 23(b)(3)* IND MedMon Class meet *Rule 23* requirements. In particular, they contend:

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[30] These include: either not requiring present physical injury or needing only a showing of sub cellular injury.

[31] Since the independence of a medical monitoring claim involves a decision on substantive, not procedural, state law, and since there is no substantive federal common law on a medical monitoring claim, plaintiffs' argument on its face does not encroach upon the *Erie* doctrine. However, plaintiffs do not address the practical concern: in supplying missing state law, some Federal Courts prefer to construe it conservatively, which leaves open a pathway for incongruous decision-making if Courts from different Circuits interpret a state's substantive law dissimilarly.

1) both *Rule 23(b)(2) M*edMon classes seek a group remedy that is predominantly injunctive or declaratory;
(2) all MedMon classes maintain that a singular cause for relief sought, defendants' conduct, applies to the entirety of the class; and
(3) in no MedMon class is there individualized treatment sought by individual class members.

Plaintiffs further argue that, even though a medical monitoring program involves payment to a medical testing agency/provider to analyze results, the essential nature of medical monitoring is not damages relief. Seeking no particular amount of damages, plaintiffs declare that medical monitoring is equitable in nature, and they therefore are seeking what is tantamount to an injunction that stipulates defendants provide plaintiffs monitoring, which parenthetically must be paid for.

Defendants counter that no proposed MedMon class meets *Rule 23* requirements. They argue the great variability in the facts of each plaintiff's nitrosamine exposure—such as exposure levels, medical histories, whether for each plaintiff there is an actual need for, and benefit to, monitoring, and for how long—coupled with the variability in state law standards not only defeats cohesiveness under *Rule 23(b)(2)* but also precludes predominance under *Rule 23(b)(3)*.

Defendants further argue certification for both IND and REM MedMon classes commands review under *Rule 23(b)(3)*, not *23(b)(2)*. They assert medical monitoring is improper for class certification under *23(b)(2).* Defendants aver *Rule 23(b)(2)* was intended to give broad declaratory / injunctive relief in civil rights cases that seek to protect an amorphous class of persons who, since they often cannot be noticed, are in fact not noticed, and concomitantly cannot opt out of the class. Defendants also contend that medical monitoring essentially seeks money damages to pay for the medical testing, analysis, and reporting, thereby making certification under *Rule 23(b)(2)* improper. They again predict that the great variability in the facts of each plaintiff's nitrosamine exposure coupled with the variability in state law standards can only defeat cohesiveness under *23(b)(2)*.[32]

Since plaintiffs seek certification of the IND MedMon class under both *Rules 23(b)(2) and (3)* and a REM class under *Rule 23(b)(2)*, the Court finds it prudent to examine *Rule 23(b)(2)* certification issues first to avoid any unintended estoppel effects on any MedMon class. *See* Table 6 *infra*.

5.3 *RULE 23(b)(2)* CONSIDERATIONS

5.3.1 *Rule 23(b)(2)* Requirements

The Third Circuit has distinguished between classes certified under *Rule 23(b)(3)* and *Rule*

[32] and, they also argue, likewise precludes predominance under *23(b)(3).*

23(b)(2) in that "these two subsections actually create two remarkably different litigation devices." *Shelton v. Bledsoe*, 775 F.3d 554, 560 (3d Cir. 2015). Certifying a class under *Rule 23(b)(2)* requires " 'the indivisible nature of the injunctive or declaratory remedy [to be] warranted—the notion that the conduct is such that it can be enjoined or declared unlawful only as to all of the class members or as to none of them.' *Wal–Mart [Inc. v. Dukes]*, 131 S.Ct. [2541] at 2557 (*quoting* Richard A. Nagareda, *Class Certification in the Age of Aggregate Proof*, 84 N.Y.U. L. REV. 97, 132 (2009))". *Shelton*, 775 F.3d at 560. Only when a single injunction / declaratory judgment can provide relief to each member of the class does *Rule 23(b)(2)* apply. *Wal-mart*, 564 U.S. at 360.

Since *Rule 23(b)(2)* class members lack the right to opt out of the class, significant, individualized issues in the class action can undermine the manageability of the class and its overall value as a litigation mechanism. Consequently, the Third Circuit has imposed the requirement that a *Rule 23(b)(2)* class action be cohesive (*Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 143 (3d Cir.1998), particularly, as to those claims tried in the class action. *Wetzel v. Liberty Mutual Insurance Company*, 508 F.2d 239 (3d Cir.1975). The cohesiveness requirement[33] implicates neither member ascertainability (*Shelton*, 775 F.3d at 563), predominance, nor superiority. *Wal–Mart*, 564 U.S. at 362. As long as the *23(b)(2)* class is clearly defined, the class may be enforced without requiring identification of individual class members.[34] However, "[b]ecause of the cohesive nature of the class…all members of the [*Rule 23(b)(2)*] class will be bound" and therefore "[u]nnamed members with valid individual claims [lack] the opportunity to withdraw and may be prejudiced by a negative judgment in the class action."[35] *Barnes*, 161 F.3d at 143. Courts therefore have been advised to be less liberal in granting class certification under *Rule 23 (b)(2)*. *Ibid. citing Santiago v. City of Philadelphia*, 72 F.R.D. 619, 628 (E.D.Pa.1976).

In sum, the Third Circuit has defined a proper *Rule 23(b)(2)* class as:

(1) meeting the requirements of *Rule 23(a)*;[36]

(2) sufficiently cohesive under *Rule 23(b)(2)* and the Circuit's guidance in *Barnes*, 161 F.3d at 143; and

(3) capable of description by a "readily discernible, clear, and precise statement of the parameters defining the class," and the Circuit's discussion in *Wachtel ex. Rel. Jesse v. Guardian Life Ins. Co. of America]*, 453 F.3d 179, 187 (3d Cir. 2006).

Shelton, 775 F.3d at 563.

In addition to cohesiveness and a readily discernible statement of the class-entry boundary

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[33] Arises from *Rule 23(b)(2)* itself: A class action is maintainable under *Rule 23(b)(2)* when "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." *Fed.R.Civ.P. 23(b)(2)*.

[34] "If relief is granted … the defendants are legally obligated to comply, and it is usually unnecessary to define with precision the persons entitled to enforce compliance, since presumably at least the representative plaintiffs would be available to seek … relief if necessary." *Rice v. City of Phila.*, 66 F.R.D. 17, 19 (E.D.Pa.1974).

[35] that is, inadvertent issue preclusion.

[36] Numerosity, commonality, typicality, representativeness of named class representatives.

condition, the *Rule 23 (b)(2)* class must seek primarily non-damages relief as the sole, universally-enforced relief. A claim for monetary relief must be incidental to the requested injunctive/declaratory relief and will entail "no complex individualized determinations." *Allison v. Citgo Petroleum Corp.*, 151 F.3d 402, 415 (5th Cir.1998). The Third Circuit has declared incidental damages to "flow directly from liability to the class ***as a whole*** on the claims forming the basis of the injunctive or declaratory relief" and may not be computed by standards reliant upon "the intangible, subjective differences of each class member's circumstances [citation omitted]." *Barabin v. Aramark Corp.*, 02-cv-8057, 2003 WL 355417 at *2 (3d Cir. 24 Jan 2003) [emphasis in the original].

Some courts in this Circuit have reviewed whether to certify a *Rule 23(b)(2)* class when medical monitoring was the requested injunctive /declaratory relief. Relying on Third Circuit guidance, the *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine*) Products Liability Litigation Court ["In re Diet Drugs MDL"],[37] found that a court-supervised program in which class members get periodic medical examinations to early detect disease is a "paradigmatic request for injunctive relief." MDL 1203, 2000 WL 1222042, at *54 (E.D. Pa. 28 Aug 2000) [*quoting Barnes*, 161 F.3d at 132] . Moreover, upon summarizing *Barnes'* guidance and applying it to medical monitoring as a remedy,[38] the *In re Diet Drugs* MDL Court certified both a *Rule 23(b)(2)* and a *Rule 23(b)(3)* class for medical monitoring in its proposed Class Action Settlement Agreement, especially because there was a relatively easy and scientifically well-known method for detection. However, the potential estoppel problems in a *Rule 23(b)(2)* class were resolved in the *In re Diet Drugs* MDL by the overlying Class Action Settlement Agreement. This is not the situation here, where there is no Class Action Settlement Agreement; thus, the Court finds *In re Diet Drugs* a not entirely helpful example of a double class certification.

5.3.2 Estoppel Issues Relating to *Rule 23(b)(2) Classes*

This Court finds neither party has sufficiently addressed these possible estoppel issues:

1) Possible estoppel effect by the *23(b)(3)* IND MedMon class on the *23(b)(2)* IND MedMon class. Neither party has raised whether the loss of medical monitoring <u>damages</u> for a *Rule <u>23(b)(3)</u>* IND MedMon class member may trigger a corresponding loss of <u>injunctive / declaratory relief</u> for a *Rule*

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[37] This MDL concerned the biological *sequelae* from taking certain diet drugs for the relevant duration, for which plaintiffs sought medical monitoring via a *Rule 23(b)(2)* class certification. Any negative caselaw treatment for the enforcement of the Class Action Settlement in this matter does not relate to or affect the legal propriety of the *In re Diet Drug* Court's certification of the *Rule 23(b)(2)* class.

[38] "(1) plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant;
(2) as a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious asymptomatic disease;
(3) that increased risk makes periodic diagnostic medical examinations reasonably necessary;
(4) monitoring and testing procedures exist that make the early detection and treatment of the disease possible and beneficial; and
(5) a reasonable physician would prescribe a monitoring regime different than the one that would have been prescribed in the absence of that particular exposure."
In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation., MDL1203, 2000 WL 1222042, at *54 (E.D. Pa. 28 Aug 2000) [*citing Barnes,* 161 F.3d at 138 fn. 10 (*citing In re Paoli Railroad Yard PCB Litig.*, 916 F.2d 829, 852 (3d Cir.1990)) and *In re Paoli Railroad Yard PCB Litig.*, 35 F.3d 717, 788 (3d Cir.1994)].

23(b)(2) IND MedMon class member, especially because these two classes contain the same members. *See* Table 6 *infra*.

2) Possible estoppel effect of the *23(b)(2)* IND MedMon class on the *23(b)(2)* REM MedMon class in jurisdictions where a *23(b)(2)* IND MedMon class member has lost the right to medical monitoring injunctive relief. In short, what effect does the loss of a medical monitoring injunctive remedy for an Independent claim have in those same jurisdictions where members seek the same remedy but for an accompanying legal claim?

3) Possible estoppel effect of the *23(b)(2)* IND MedMon class on later personal injury damages claims. Put differently, could the loss of a medical monitoring injunctive remedy affect the *23(b)(2)* class member's eligibility for personal injury damages for a cancer-caused death because of the loss of medical monitoring, which imposed an intervening cause of the class member's death? [39]

At this point in the litigation, estoppel issue (3) appears wholly unpredictable: all MedMon class members are by definition still alive; and none may ever succumb to cancer that is in part attributable to their ingestion of VCDs. Therefore, the Court acknowledges but does not consider this issue in its discussion *infra* on estoppel.[40]

[39] The *In re Thalomid & Revlimid Antitrust Litigation* Court noted that a potential preclusive effect any injunction granted for the class could have on subsequent individual actions for damages should be considered when analyzing a motion for class certification under *Rule 23(b)(2)*). Civil Action No. 14-69972018 WL 6573118 at *25 (D.N.J. 30 Oct 2018).

[40] A recent case in this District, *C.P. v. New Jersey Department of Education*, 19-cv-12807, 2022 WL 3572815, at *8-9 (D.N.J. 19 Aug 2022) concerned *Rule 23(b)(2)* class certification not for medical monitoring, but for enjoining the NJ Dept of Education from implementing without Court approval new procedures for due process hearings in cases involving special needs students. There, Judge Hillman expressly considered estoppel issue (3) above because the future damage claims in *CP* would most likely focus on whether the Dept. of Education had to compensate needy, eligible students for not providing adequate special education and the resultant consequences.

Persuaded by the reasoning in *Gooch v. Life Invs. Ins. Co. of Am.*, 672 F.3d 402 (6th Cir. 2012), Judge Hillman ruled that "a judgment on the Rule 23(b)(2) class's claims would not necessarily extinguish the rights of individual class members to later pursue separate damages actions". *C.P.*, 2022 WL 3572815, at *8-9. The *Gooch* Court had reasoned that "certifying declaratory relief under *Rule 23(b)(2)* is permissible even when the declaratory relief serves as a predicate for later monetary relief, which would be certified under *Rule 23(b)(3)*." 672 F.3d at 429.

Citing *In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 578 (E.D. Tenn. 2014), Judge Hillman appreciated that no Court has a crystal ball with which to declare definitively the *res judicata* effects of a decision not yet rendered, which is really a matter only for the Court presented with such a subsequent action. But the important point for the class certification motions here is that Judge Hillman did the diligent review needed and was satisfied that certification of the *23(b)(2)* class would not *per se* preclude future damages actions.

Table 6: Comparison of MedMon Classes Sought and Possible Estoppel Effect Caused by Certifying IND MedMon under *Rule 23(b)(2)*

Class	Definition	Relief Sought	Where Relief is Sought	Estoppel Effect[41]
23(b)(3) IND	those who ingested during relevant duration an LCT of NDMA / NDEA from VCDs AND reside within U.S jurisdictions where law permits medical monitoring as independent legal claim	Damages Relief for Medical Monitoring as Separate Claim, INDEPENDENT of any other pleaded claim	Alaska, Arizona, Colorado, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Maine, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, West Virginia, Wyoming	IF *23(b)(2)* IND class members lose MedMon rights, THEN so may *23(b)(3)* IND class members because both IND classes comprise SAME members
23(b)(2) IND	Same as above	**ONLY** Injunctive / Declaratory Relief: : Approved Medical Monitoring Program that requires creating fund to pay for medical testing & exams.	Same as above	IF *23(b)(3)* IND class members lose MedMon rights, THEN so may *23(b)(2)* IND class members because both IND classes comprise SAME members
*23(b)(**2**)* REM	those who ingested in relevant duration an LCT of NDMA / NDEA from VCDs and reside in U.S. jurisdictions where law permits medical monitoring only as remedy to accompanying claim.	**ONLY** Injunctive-Declaratory Relief in form of: Approved Medical Monitoring Program, which requires creating fund to pay for medical Checkups & testing	Specifically included are relevant individuals residing in **every U.S. land**, **except Mississippi.**	IF *23(b)(2)* IND class members lose MedMon rights, to medical THEN so may those *23(b)(2)* REM class members in same jurisdictions as listed in *23(b)(2)* IND class.

[41] *See supra,* for discussion on *Rule 23(b)(2)* class certification requirements.

. This Court has reviewed the available jurisprudence as it relates especially to estoppel issue (1) in Table 6 *supra* in deciding which of the three MedMon classes to certify. To say that such jurisprudence is a jumble of differing opinions and predictions grossly understates, largely because of the difficulty to project into the future the legal effect from the loss of injunctive / declaratory relief onto the same kind of relief or onto damages claims.

Whether adjudication of a *Rule 23(b)(2)* class action automatically bars a later action for damages for the same claim is the key consideration in certifying a *Rule 23(b)(2)* class. Since the Third Circuit has yet to rule definitively about such preclusive effect, this Court has found a few cases within the Circuit that have wrestled with this issue. Interestingly, these courts have reached different conclusions about whether to certify a *Rule 23(b)(2)* class. This jurisprudence is summarized at the footnote.[42]

5.4 *RULE 23(b)(2)* IND MedMon CLASS

To cut to the chase, this Court incorporates the *Processed Egg Products* guidance (*see* fn. 42): that a court must apply careful diligence in certifying a *Rule 23(b)(2)* class and *23(b)(3)* class that are

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[42] In *In re OSB Antitrust Litigation,* No. 06–826, 2007 WL 2253425, at *17–18 (E.D. Pa. 3 Aug 2007), the court agreed with plaintiffs that the claims for damages and injunctive relief were entirely separate and that the *23(b)(2)* class would not necessarily extinguish the rights of individual class members to later pursue separate damages actions. Differently from here, the two proposed classes arose under different statutes—the Clayton Act versus state statutes—and comprised a nationwide class and state law classes. Since the nationwide class potentially included many members from states that prohibited damages actions, many of that class sought injunctive relief only. Therefore, since the nationwide class was generally precluded from bringing prohibited damages actions, the court saw the two classes—national and state law-- had a "ingrained" estoppel boundary. There is no such ingrained estoppel boundary here as medical monitoring and personal injury claims arise under state law.

The court in *In re Processed Egg Products*, MDL 2002, 312 F.R.D. 124 (3d Cir. 2015*)* refused to certify a *Rule 23(b)(2)* class along with a *Rule 23(b)(3)* class, but nonetheless gave plaintiffs the option to renew their motion for 23(b)(2) certification. *Id*. at 165. To the point, the court found that the certification of a *Rule 23(b)(2)* and a *23(b)(3)* class in which both classes include many of the same members could implicate a possible estoppel effect on later damage claims, which is precisely the concern of this Court. The *Processed Egg Products* court thoroughly reviewed the extant jurisprudence on this issue and relied heavily on the Third Circuit's approach in *Hohider v. United Parcel Serv., Inc.*, 574 F.3d 169 (3d Cir.2009) even while recognizing that *Hohider* was not on point to the estoppel issue the *Processed Egg Products* court faced.

The *Hohider* approach to certification of separate *Rule 23(b)(2)* and *Rule 23(b)(3)* classes is a diligent review of these factors:
- "the overall complexity of the case and the efficiencies to be gained by granting partial certification;
- the substantive law underlying the claim(s), including any choice-of-law questions it may present;
- the impact partial certification will have on the constitutional and statutory rights of both the class members and the defendant(s);
- the potential preclusive effect that resolution of the proposed issues class will have; and so forth."

Id. at 201–02.

Besides these Third Circuit rulings, other Circuits have found that an earlier judgment in a *Rule 23(b)(2)* class action does not *necessarily* bar later actions on damages.
See e.g. *Hiser v. Franklin*, 94 F.3d 1287 (9th Cir. 1996)[*pronouncing* "the general rule is that a class action suit seeking but declaratory and injunctive relief does not bar subsequent individual damage claims by class members, even if based on the same events." *Id*. at 1291]; *and Gooch v. Life Invs. Ins. Co. of Am.*, 672 F.3d 402 (6th Cir. 2012) [*stating:* "In sum, certifying declaratory relief under *Rule 23(b)(2)* is permissible even when the declaratory relief serves as a predicate for later monetary relief, which would be certified under *Rule 23(b)(3).*" *Id*. at 429].
But see *Zachery v. Texaco Exploration and Production, Inc.*, 185 F.R.D. 230 (W.D. Tex. 1999) [*finding* "[b]ecause there appears to be no clear cut right to opt out of a *Rule 23(b)(2)* class action, the named Plaintiffs are asking the class members being represented here to risk waiving their right to monetary damages solely so the action for disparate treatment can proceed as a class action. Although the opt-out issue has not been fully decided, the Court is unwilling to risk this result." *Id*. at 244].

twins to each other in terms of class membership and legal argument but not on *Rule 23* standards or for the remedies sought.

Accordingly, like the courts in both *In re Egg Processed Egg Products Antitrust Litigation* and *In re Thalomid and Revlimid Antitrust Litigation*, No. 14-cv-6997, 2018 WL 6573118 at *24-25 (D.N.J. 30 October 2018), this Court **DENIES WITHOUT PREJUDICE** the certification of the *Rule 23(b)(2)* IND MedMon class. Specifically, the Court grants plaintiffs the right to re-seek class certification of the *23(b)(2)* IND MedMon class if they choose to include in their renewed motion briefing on the specific estoppel effects the *Rule 23(b)(2)* IND MedMon class may have on other concurrent MedMon classes.

5.5 *RULE 23(b)(2) REM* MedMon CLASS

As discussed above, a properly certified *Rule 23(b)(2)* class demonstrates the following: a clear and precise statement of the parameters defining the class; *Rule 23(a)* requirements; sufficient cohesiveness; as well as seeks a remedy that is primarily injunctive or declaratory.

As for a class entry parameter, the list in Table 5 of LCT calculations presents a sufficiently coherent and consistent entry criterion into this class.[43] As for cohesiveness, the Court's confirmation in Table 7 *infra* of the legal standards in each jurisdiction that permits medical monitoring as a remedy for an accompanying legal claim subdivides the class into relevant subclasses.

As for *Rule 23(a)* requirements, class members are highly likely numerous beyond the minimum of 40 persons simply because of the numbers of individuals in the U.S. who took VCDs to control their hypertension. The legal claims of this class exhibit commonality and typicality in that each class member must have ingested an LCT of NDMA and / or NDEA and reside in a U.S. jurisdiction that allows a medical monitoring remedy for such exposure. Moreover, the LCT listing itself defines a required boundary around class entry, which highlights a commonality as to minimum exposure medical and reduces the importance of individualized issues of ingested VCD, dosage, and duration. In short, by using the LCT as class entry criterion, plaintiffs reduced the significance of an individual member's VCD, dosage, or duration because the cohering fact is that each member's NDMA / NDEA exposure necessitates medical monitoring as a remedy. Plaintiffs aver the named class representatives have no individual issues that could or do raise a conflict to unnamed class members (ECF No. 1750: 27) and that proposed class counsel Rachel German, Esq., has deep experience in class action litigation. *Ibid*.

More to the point on cohesiveness, the Third Circuit has found this the central factor in a *Rule 23(b)(2)* class certification. *Barnes*, 161 F.3d at 143. A class is cohesive when the "class's claims are

[43] To reiterate, the R*ule 23(b)(2) REM M*edMon class includes those individuals who have ingested from 1 January 2012 until the last VCD recall an LCT of NDMA or NDEA from prescribed VCDs and who also reside in U.S. states, territories, or possessions where the state law permits medical monitoring only as a remedy to an accompanying legal claim. This class specifically includes those relevant individuals residing in every U.S. state, territory, and possession, except Mississippi.

common ones and that adjudication of the case will not devolve into consideration of myriad individual issues." *In re Processed Egg Products Antitrust Litigation*, MD 08-2002, 312 FRD 155, 169 (E.D. Pa. 2015 [*quoting* Newberg on Class Actions § 4:34 (5th Ed.)]. Specifically, *Rule 23(b)(2)* class certification does NOT entitle each individual class member to a *different* injunction or declaratory judgment against the defendant. *Wal-Mart,* 564 U.S. at 360-361. Cohesiveness arises from plaintiffs' showing that the injunctive / declaratory relief[44] of medical monitoring is appropriate to the entire class and raises no overt or expressly individualized issues at this point.

In styling their medical monitoring program as a unitary remedy, plaintiffs sum up the program as a notice broadcast intended to reach and teach all MedMon *Rule 23(b)(2)* class members about needed medical testing and the recommended periodicity of the tests. This periodicity means each class member will get various medical tests on a spelled out, regular basis to monitor for esophageal, stomach, colorectal /intestinal, liver, lung, bladder, blood, pancreatic, and prostate cancer, cancers linked to NDMA and NDEA exposure. Medical experts will review the tests to spot early, possible signs of cancer formation and disseminate their findings to the class member. Defendants will pay for the notice, testing, review, and dissemination.

Although arguing that medical monitoring as a unitary, group-wide remedy supports *Rule 23(b)(2)* cohesiveness, plaintiffs have not followed their own assertion that cohesiveness requires a showing of: 1) a reasonable need to mitigate the cancer risks; and, 2) the existence of a diagnostic evaluation program different from what would have been prescribed in the absence of the VCD exposure. ECF No. 1750: 17 [*citing In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 788 (3d Cir. 1994)].

In citing to the report of their medical expert Dr. Kaplan (*see* Section 6.0), plaintiffs have done little more than précis his recommended medical monitoring program, stating generally that each class member shall receive regular cancer screening tests to mitigate risks and based on medical necessity. They aver this proposed program needs no individualized inquiries into its benefits, or safety implications for certain class members, but is uniform in mitigating the risk faced by the entire class.[45] ECF No. 1750: 17.

But a particularly pressing problem in plaintiffs' underwhelming argument arises from the

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[44] *See supra* fn. 37 and accompanying text. In this Circuit, the *In re Diet Drugs* MDL Court ruled that medical monitoring for future, negative health consequences from drug ingestion, even though incurring costs for medical analysis and review, is not a damages remedy.

See also Gibbs v. E.I. DuPont de Nemours & Co., Inc., 876 F. Supp. 475 (W.D. N.Y. 1995, a case outside of this Circuit, in which plaintiffs sought "a court-administered fund paid for by defendants which would cover the reasonably anticipated costs of a medical monitoring program for bladder cancer for the lifetime of the class members." *Id.* at 477. The *Gibbs* court rejected defendants' argument that their payment of money into a fund was monetary relief and reasoned that "[a] court-administered fund that goes beyond payment of the costs of monitoring an individual plaintiff's health to establish pooled resources for the early detection and advances in treatment of the disease is injunctive in nature rather than 'predominately money damages' and therefore is properly certified under *Rule 23(b)(2)*." *Id.* at 481.

[45] Plus, plaintiffs assert their program is administratively feasible—there is well-established infrastructure to provide notice, and to conduct the contemplated tests and screenings. Defendants will be able to track communications to their customers. However, administrative feasibility is not a requirement of *Rule 23(b)(2)* classes.

practical fact that a *Rule 23(b)(2)* class member need not enroll affirmatively into the class because such class membership is automatic. The Court, therefore, sees that automatic class membership conveys nothing to the members about how they will participate in real terms in a medical monitoring program that can impart "cohesiveness" to the class. Particularly absent are details about ensuring that putative class members are adequately apprised of the cancer risk and hence of the need to undergo the periodic testing directed by the program. In addition, plaintiffs give equally scant specifics about how class members actually sign up for the program, get specific education about it, receive benefit from it, and / or get informed on how it minimizes their risk. In essence, a great many details are lacking as to the execution of the program, including the guarantee that the program actually works by providing the offered benefit—the earliest and prompt observation of cancer development. This lack calls attention to plaintiffs' expectations that a medical monitoring program will create a "cohesive" class largely because it offers a "cohesive" medical benefit, which their brief largely glosses over. But, it does not follow logically that the mere creation of such a program automatically applies a unified and consistent remedy to a group of individuals automatically inducted into a class about which they are not required to be noticed.

Other than seeking a "court-supervised" program, plaintiffs' gives no more than a bare-bones account of it. ECF No. 1750: 17. It is only the report of plaintiffs' class certification expert, Dr. Kaplan, that sets forth certain medical tests[46] that presumably make up plaintiffs' medical monitoring "program" which rescues plaintiffs' minimalist "cohesiveness" argument. The Court finds that plaintiffs' less than modest description together with the details of testing and medical analyses in Dr. Kaplan's report are just enough to show that the class is cohesive in terms of the injunctive / declaratory remedy sought.

Another issue relating to the cohesiveness of the *Rule 23(b)(2)* REM MedMon class is the possible exclusion of putative class members because of the variability in state law rulings on medical monitoring as a remedy. Notably, the *In re Diet Drugs* court ordered plaintiffs to brief the varying state law requirements with the understanding that the court's grant of class certification would change as needed to create subclasses based upon state law variance of both medical monitoring law and differences in the underlying claims of strict liability, negligence, and breach of warranty. *In re Diet Drugs*, MDL 1203, 1999 WL 673066, *16-*17 (E.D. Pa. 26 Aug 1999).[47] The *In re Diet Drugs* court required this because it noted asymptomatic plaintiffs whose claims lay in jurisdictions that require an

[46] Every 5 years: Galleri® Cancer signal detection test plus Cologuard® or similar fecal testing plus Upper endoscopy; and Annually: Low Dose CT lung scan. Periodicity of the testing does not change appreciably for individual, specific risk factors, such as smoking, etc.

[47] *In re Diet Drug* plaintiffs had not briefed the court on the issue of varying state law, having assumed Pennsylvania law applied to the entire class.

Cf. In re West Virginia Rezulin Litigation, 214 W. Va. 52 (2003) [*reversing* denial of *Rule 23(b)(2)* medical monitoring class in product liability action regarding diabetes drug and *stating* "after liability has been established, a court may exercise its equitable powers to establish and administer a court-supervised medical monitoring program to oversee and direct medical surveillance, and provide for medical examinations and testing of members of a class"].

injury for a tort claim would be excluded from the class. *Ibid.*

Unlike in *Diet Drugs*, the parties here have already provided the Court with tables of state law requirements for medical monitoring as a remedy in order to fine tune which U.S. jurisdictions may be included in this class. Moreover, the Court's own research, relying on defendants' tables of state law opposing plaintiffs' subclasses, confirms those US jurisdictions that permit medical monitoring remedy for accompanying legal claims and is listed in Table 7.

Considering defendants' arguments that there is too much variation in state law as well as in each plaintiffs' fact particulars of dosage, VCD, and duration to certify this class as cohesive, the Court finds Table 7 sufficiently accommodates the state law variability and plaintiffs' fact variation by subdividing this *Rule 23(b)(2)* REM MedMon class into legally relevant subclasses. Also considering defendants' arguments expressed in the next section *infra* that the LCT is not a scientifically rigorous calculation, the Court nonetheless finds that each putative class member's expression of an LCT as calculated in Table 5, is a unifying class entry criterion. Hence, it imparts cohesiveness to this class even if ultimately the LCT calculation relies on statistical assumptions about the quantity of nitrosamine in each VCD ingested.

Accordingly, the Court **GRANTS** plaintiffs motion to certify a *Rule 23(b)(2)* MedMon REM class divided into those subclasses listed in Table 7.

5.6 *RULE 23(b)(3)* IND MedMon CLASS[48]

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5.6.1 *Rule 23(a)* Requirements

5.6.1.1 Numerosity

As with the EcoLoss classes, plaintiffs argue FDA recalls include over 1,200 NDCs of contaminated VCDs; Pharmacies' and Iqvia data show more than 988,183 individuals filled VCD prescriptions during the relevant period. Thus, the classes are easily presumed sufficiently numerous, which defendants do not dispute.

Accordingly, the Court finds this requirement met.

[48] To reiterate, the *Rule 23(b)(3)* IND MedMon classes include those individuals who ingested an LCT of NDMA or NDEA from contaminated VCDs and who reside in U.S. jurisdictions where the law permits medical monitoring as a legal claim independent of any other claim pleaded in the litigation. This class can include relevant individuals residing in Alaska, Arizona, Colorado, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Maine, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, West Virginia, Wyoming.
Excluded jurisdictions for this class are: Alabama, Arkansas, California, Connecticut, Georgia, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Mississippi, Nebraska, New Jersey, Ohio, Oklahoma, South Carolina, Tennessee, Texas, Virginia, Washington, and Wisconsin.

5.6.1.2 Commonality

Plaintiffs argue that there are two legal / factual issues common to the entire putative class, viz., the need for medical monitoring and the evidence to show that need. Both issues devolve to a class member's LCT calculation. Defendants have raised no objection. Accordingly, the Court finds this requirement met.

5.6.1.3 Typicality

Plaintiffs argue the named representatives bring similar claims, seek the same relief, live in states that recognize medical monitoring as an independent claim, and have ingested an LCT that triggers their entry into the class as well as the need for medical monitoring. Defendants assert that material variations of state law that prohibit a stand-alone monitoring claim foreclose a finding of typicality. Specifically, these material variations include the need to show present physical injury, evidence of a procedure that detects a specific cancer at the physical or subcellular level, and the existence of a treatment for it.

In evaluating typicality, courts in this Circuit focus on the differences between the class representatives' facts and claim(s) and those of the unnamed class members. However, differences alone in fact situations between the unnamed and named plaintiffs do not render a claim atypical so long as the plaintiffs' claim arises from the same events, practices, or course of conduct of the defendants, and is based upon the same legal theory. *Stewart*, 275 F.3d at 227–28.

Here, all named representatives seek a common remedy in the form of a medical monitoring program. Each named representative must have ingested VCDs in an amount that meets one of the calculated variations of Lifetime Cumulative Threshold required for membership in this class. That state law varies as to the essential elements of medical monitoring as an independent claim does not resolve the inquiry into fundamental differences between unnamed class members and named representatives. The nature of the remedy sought does not differ among class members; it's the applicability of that remedy that differs according to the legal requirements of the jurisdiction where they reside. Plaintiffs' breakdown of this class into subclasses depending on the variability in state law standards helps to diminish the detectable, but not distinctive, differences between named representatives and unnamed class members. Accordingly, the Courts finds this requirement met.

5.6.1.4 Adequacy

Plaintiffs argue no conflict of legal interest exists between named class representatives and

unnamed class members. All putative class members share the same need for the same relief: monitoring of potential cancer development. The proposed class counsel are Rachel Gelman, Esq., a partner in the New York office of Lieff, Cabraser, Heimann & Bernstein, LLP, whose firm practice focuses on, *inter alia*, complex and class action litigation involving product liability / mass torts, and Nicholas Migliaccio, Esq., a founder of Migliaccio & Rathod LLP, a Washington DC firm that focuses on, *inter alia*, class actions, including several concerning products liability. Ms. Gelman is a member of the Plaintiffs' Steering Committee in this MDL. Both proposed counsel are well-versed in prosecuting complex actions; and, their firms have committed sufficient resources to prosecuting the case. Defendants have raised no objection. Accordingly, the Court finds this requirement met.

5.6.2 *Rule 23(b)* Requirements

5.6.2.1 Preponderance

Plaintiffs state that *Redland Soccer Club, Inc. v. Dep't of the Army & Dep't of Def. of the U.S.*, 696 A.2d 137, 145-46 (1997) reliably sets forth the legal framework for deciding if medical monitoring stands as an independent cause of action. They aver several cases[49] in other jurisdictions have relied on it, which the Court's research[50] bears out. Plaintiffs' use the *Redland* framework here to assert that the legal issues and facts common to the *23(b)(3)* IND MedMon class predominate over individualized ones.

The *Redland* framework includes:

"(1) exposure greater than normal background levels; (2) to a proven hazardous substance;
(3) caused by the defendant's negligence;
(4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a

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[49] Following are the cases plaintiffs cited in their brief for certification of this class (ECF No. 1750:24, fn.12):
In the 6th Circuit: *In re Welding Fume Prods. Liability Litig.*, 245 F.R.D. 279, 292 (N.D. Ohio) (finding that elements of medical monitoring claim in Arizona, Ohio, and Pennsylvania were all substantially similar);
In the 10th Circuit: *Bell v. Three M Company.*, 344 F. Supp. 3d 1207, 1225 (D. Colo. 2018) (listing identical elements of medical monitoring claim);
In the 2nd Circuit: *Abbatiello v. Monsanto Co.*, 522 F. Supp. 2d 524, 539 (S.D.N.Y. 2007) (finding that New York would recognize medical monitoring claim using elements identical to those in *Redland*).

[50] In seeking guidance on the proper framework for analyzing medical monitoring as an independent claim in Pennsylvania, the Pennsylvania Supreme Court relied on the Third Circuit's rulings in *In re Paoli Railroad Yard PCB Litigation,* 916 F.2d 829 (3d Cir.1990) (*Paoli I*), *In re Paoli Railroad Yard PCB Litigation,* 35 F.3d 717 (3d Cir.1994) (*Paoli II*) and on the Superior Court's (trial court) *Redland* decision to enumerate the elements listed *supra*. *Redland,* 696 A.2d at 145-146. Because of its meticulousness, the *Redland* opinion has served as a template for other courts in varying Circuits in analyzing whether the predominance requirement of *Rule 23(b)(3)* is met for medical monitoring as an independent claim.

In addition to those cases cited by plaintiffs and listed in fn. 49, *supra*, the Court adds a smattering of cases here from other jurisdictions and circuits which have acknowledged that *Redland's* list of predominance factors was the gold standard.

These include:
In the 4th Circuit: *Bombardiere v. Schlumberger Technology Corp.*, 934 F.Supp 843, 851 (N.D. W.Va. 2013);
In the 5th Circuit: *Leib v. Rex Energy Operating Corp.*, No. 06-cv-802, 2008 WL 5377092 at *12 (S.D. Ill. 19 Dec 2008);
In the 8th Circuit: *Thompson v. American Tobacco Co.*, 189 F.R.D. 544, 551 (D. Minn. 1999); *Meyer ex rel. Coplin v. Fluor Corp.*, 220 S.W. 3d 712, fn. 6 (Mo. 2007) (*en banc*);
In the 9th Circuit: Sadler v. Pacific Care of Nevada, 340 P.3d 1264, 1271 (Nev. 2014);
In the 11th Circuit: *Bourgeois v. A.P. Green Industries, Inc.*, 716 So. 2d 355, 360 (La. 1998).

serious latent disease;
(5) a monitoring procedure exists that makes the early detection of the disease possible;
(6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and
(7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles." *Redland,* 696 A.2d at 145-46.

In a summary judgment context, the *Redland* Court assembled these elements as the legal standard for deciding if a plaintiff had shown that medical monitoring could be pleaded as an independent claim in Pennsylvania. Thus, in summary judgment contexts, courts use the *Redland* framework to decide if medical monitoring can stand as an independent claim. However, in a class certification context as here, the *Redland* elements need not be "proven", but serve as a useful heuristic to bear out that common legal issues and facts of an independent medical monitoring claim predominate across the class.

Going through this framework, plaintiffs assert that, as for exposure greater than normal to a proven hazardous substance, the LCT both indicates and confirms heightened nitrosamine exposure. Thus, according to plaintiffs, *Redland* elements 1 and 2 necessarily apply to all MedMon class members. As for *Redland* element 3, plaintiffs assert a common theme: that it is defendants' conduct—through negligence or breach of warranty or fraud or violation of consumer protection statutes—that resulted in the NDMA/NDEA contamination of the VCDs ingested by all MedMon class members. Plaintiffs contend that *Redland* elements 4 and 5 dominate throughout the entire class because the LCT confirms heightened nitrosamine exposure. As for *Redland* elements 6 and 7, plaintiffs state these elements blend into each other in that the scientific community both recognizes that, because of the LCT, the kind of medical monitoring for class members differs from ordinary medical care and has developed such programs to early-detect the presence of cancer cells.

Defendants respond that certain, important facts relating to the medical monitoring claims are highly individualized. These include whether class members have been exposed to "sufficiently high" levels of NDMA/NDEA through their ingestion of VCDs to warrant medical monitoring as an independent claim. This assertion is in essence an implied causation argument in which defendants point to the unknown and individualized factor of whether the ingestion of the nitrosamine genotoxins from VCDs will actually tip a class member's probability of cancer development into the "urgent zone" of medical monitoring.

No answer to this question—how did VCD ingestion up one's cancer risk—can be given through either facts or law. Moreover, the Court understands the scientific community itself cannot tease out a single, individual cause of cancer from a lifetime of nitrosamine exposure from various sources. Nor

can the scientific community determine the cause of an inflection point making one's likelihood of developing cancer more and more probable. The irony in defendants' argument is that it points in a general way to what the scientific community for the last 30 years has published about nitrosamine exposure: that a probable increase in cancer development is attributable to an increase in exposure to nitrosamines—via VCD ingestion, inhalation, etc. Thus, defendants' implicit causation argument works to support that there are common facts and legal issues for the entire MedMon class, thereby supporting predominance.

Given that the precise increase in cancer risk caused by VCD ingestion may be unknowable, defendants raise doubts whether a proposed medical monitoring program is medically necessary or even appropriate for each putative class member. Defendants further question whether all or even any VCDs were likely to raise a putative class member's risk of cancer, which in effect poses a legal causation issue common to the entire class. And, again, although the precise increase in cancer risk due to ingestion of VCDs, and therefore the overall increase in cancer risk, is unknowable, every class member shares a common legal question that need not be resolved at this stage, viz. the possibility of an increased cancer risk as well as an increased fear that class members have such a higher risk. Ironically, again, that shared fear and possibly shared risk predominate across the class and are alleviated commonly by a medical monitoring program that applies to all members.

Defendants also assert that such a medical monitoring program will not apply equally to all members in terms of the variability of services and costs in testing, analysis, and examination. This variability can be attributable to varying medical care pricing in different locations and to variability in testing efficiency and in the testing preferences of individual treating physicians. Although different regions of the country have differing levels of medical expertise, the Court envisions that an overall medical monitoring program as described by plaintiffs' expert Dr. Kaplan would apply generally to all class members and therefore dominates throughout the class.

Accordingly, the Court finds the *23(b)(3)* IND MedMon class meets the predominance requirement.

5.6.2.2 Superiority

Plaintiffs assert *Rule 23(b)(3)(A)* supports certification because an individual class member can have no incentive to pursue a separate litigation for the independent claim of medical monitoring. The litigation costs and efforts to bring an individual lawsuit would be enormous compared with the returns: the cost of regular medical testing, analysis, and review. The Court also considers its discussion *supra* in sections 3.3.2 and 4.3.2, which relates to similar reasons why members of Economic Loss Classes would not bring individual suits against defendants. In effect, an individual action against

defendants for medical monitoring as an independent claim would not be a rational effort. The meagerness of the individual remedy and the needed efforts to achieve it underscores the opposition that any individual litigator faces against the multitude of defendants here.

All the reasons discussed *supra* in sections 3.3.2 and 4.3.2 why class certification is a superior adjudication strategy in terms of fairness and efficiency (*In re Prudential Ins. Co. of Am. Sales Practices Litig.*, 148 F.3d at 316*)* apply even more so here. These reasons include this Court's expertise and experience, that this action as an MDL bars any individual litigation until resolution of discovery and bellwether trials, and the sheer number of plaintiffs who ingested VCDs who may be facing increased risks of cancer incidence, even if that precise increase in risk is unknown. Because of the much weightier fairness and efficiency considerations of adjudicating the claims of the putative class against very large and many defendants, this Court is reminded that "[t]he core purpose of *Rule 23(b)(3)* is to vindicate the claims of consumers and other groups of people whose individual claims would be too small to warrant litigation." *Smilow v. Southwestern Bell Mobil Systems, Inc.*, 323 F.3d 32, 42 (1st Cir. 2003).

Accordingly, the Court finds the *Rule 23(b)(3)* IND MedMon class meets the superiority requirement.

5.6.2.3 Ascertainability

Regarding this requirement, it may be useful to restate the Third Circuit's guidance: "The ascertainability inquiry is two-fold, requiring a plaintiff to show that: (1) the class is 'defined with reference to objective criteria'"; and (2) there is 'a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.' [*Carrera*, 727 F.3d] at 355 (*citing Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 593–94 (3d Cir. 2012))." *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3rd Cir. 2015).

Further, it "does not mean that a plaintiff must be able to identify all class members at class certification—instead, a plaintiff need only show that "class members *can* be identified." *Carrera*, 727 F.3d at 308 n. 2 (emphasis added)." *Byrd*, 784 F.3d. at 163. What the Third Circuit has read into *Rule 23(b)(3)* for feasible ascertainability is not a perfectly-drawn, rationally logic classification system[51] akin to an Aristotelian scheme that imposes in top-down fashion a genus category on a class of individuals and then within that genus enforces definitive, absolute differences between species, which apply for all space and time.

Rather, the Third Circuit's guidance leans towards an empirical approach to class certification.

[51] Similar to that espoused by Aristotle: with genus and species, where species was defined and differentiated by conclusive difference.

Akin to cladistics[52], this kind of class certification scheme adopts a bottom-up approach and lumps observable, shared characteristics to place individuals into narrowly drawn, upwardly-nested categories. A downside of this scheme is the inability to create absolute entry conditions for class members because the selected characteristics are based on observable features not necessarily inherent, and may lead to less than perfect class membership.

Empirical classification is done in everyday life and yields not perfect groupings but rather statistically significant ones. Its primary benefit is the creation of a relatively closed class boundary that excludes those individuals NOT bearing the selected characteristic(s). But, if the selected characteristic that lumps individuals into groups is not refined enough to simulate a group possessing a real-world trait, then empirical classification leads to fundamental uncertainty as to the correctness of class definition. Moreover, empirical classification is often used when the universe of possible class members share a group of similarities but not all of the same similarities. Thus, there may be "revolving" similarities across the member universe.

The Court has digressed into a discussion of systematics because it relates to each parties' arguments regarding ascertainability of this class.

For the "objective" criterion, plaintiffs rely on the LCT (*see* Table 5 *supra*) and imply it identifies accurately membership into the *Rule 23(b)(3)* IND MedMon class. However, the LCT, as defendants argue, is not scientifically rigorous. If defendants are correct, the LCT cannot serve as a defining class entry criterion, but only as an exclusion criterion that separates member from non-member, and so identifies class membership by keeping out those who are not members. Moreover, if defendants are correct, the LCT only can create a class that contains various groupings of members, each grouping having a different statistical probability of being correctly identified as class members.

Importantly, these groupings are not at all the same as plaintiffs' proposed subclasses. Rather, these groupings of class members are organized around the LCT calculations themselves. The higher the LCT number, the more likely the LCT itself has an increased statistical probability of accuracy, and therefore identifies with greater probability an individual with an increased cancer risk and who thus belongs in this *Rule 23(b)(3)* IND MedMon class. Likewise, the lower the LCT number, the statistical probability that the LCT is accurate is lower, and identifies with a lower probability an individual with an increased cancer risk and who may be placed into this class with marginal assurance.

As for their feasible mechanism for identifying class members, plaintiffs rely on these data: the pharmacy and prescription records of filled VCD prescriptions, especially on the unique 10-digit NDC code presented in those records which tags a specific drug product; and the report of their expert Dr.

[52] Exemplified in Sokal, R.R. and Rohlf, F.J., BIOMETRY, Freeman & Co., New York (4th ed. 2012)

Laura Craft (which defendants did not oppose) and which showed how to use such data to identify ConEcoLoss members. Plaintiffs argue that, as for the Economic Loss classes, this data set would likewise be a feasible mechanism for identifying *Rule 23(b)(3)* IND MedMon class members.[53] The Court recognizes that the LCT and plaintiffs' data set may imperfectly identify all those individuals who purchased VCDs (as both plaintiffs' experts Dr. Laura Craft and Dr. Rena Conti have recognized) and who would be potential class members here.

Defendants argue the LCT is an ambiguous class entry criterion that results in an ambiguously-defined class.[54] They assert that the LCT as a class defining characteristic is inherently uncertain and, in particular, the LCT calculations listed in Table 5 lack scientific rigor. This is because, without being able to connect the Lot Number to any specific VCD prescription and thus to an individual's dosage and duration, it is impossible to calculate with any degree of confidence the amount of NDMA or NDEA that an individual ingested from their VCDs. The LCT calculation based on the VCDs ingested but untethered to a Lot Number is just a calculated assumption as to what an individual's exposure to the contaminants were. Since different Lot Numbers of VCDs had differing levels of nitrosamines, defendants imply that calculating the LCT is mere extrapolating backwards from dosage and duration, which necessarily requires untested assumptions about the levels of nitrosamines in each VCD prescription. The LCT, defendants assert, cannot calculate finely enough the levels of NDMA or NDEA in each pill and is at best a statistical estimate based on assumptions about how much NDMA or NDEA each VCD contained. Defendants argue LCT cannot be an objective linchpin of ascertainability, which therefore defeats this requirement. Underlying defendants' argument is the scientific uncertainty that it is impossible to tease out which consumers ingested increased nitrosamine amounts from VCDs. Their argument boils down to: defendants cannot be held liable for medical monitoring damages because which consumers have increased risk of cancer due to VCD ingestion is unknowable.

The Court appreciates that the LCT calculation in Table 5 may with not identify all putative class members with objective ascertainability. In fact, such perfect member identification may be impossible even with a more rigorously defined LCT and also because Lot Numbers cannot be traced to individual VCD prescriptions nor can the baseline nitrosamine contamination and genetic predisposition to cancer before VCD ingestion be known. And although defendants assert below that the LCT as the class-defining criterion actually creates no reliable and class boundary, the LCT nonetheless may be

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[53] Plaintiffs cite to certain cases as examples of using combined data sets to demonstrate a feasible mechanism of ascertaining class membership. But the Court finds these irrelevant and inapposite. Plaintiffs note the court in *In re Telectronics Pacing Sys., Inc.*, 172 F.R.D. 271, 278-79 (S.D. Ohio 1997) defined the class in a similar way as here by using the model number of a pacemaker; however, that Court did NO ascertainability analysis. Neither did the Court in *Reilly v. Gould, Inc.*, 965 F. Supp. 588, 596 (M.D. Pa. 1997) as *Reilly* was decided well before the Third Circuit's jurisprudence on ascertainability. *O'Connor v. Boeing N. Am., Inc.*, 180 F.R.D. 359, 368 (C.D. Cal. 1997) concerned only predominance, which was decided in terms of commonality of the loss of property values among class members; NO ascertainability question was raised.

[54] An Aristotelean-like characteristic

boundary-creating in that it can serve to exclude non-members while the archived records of Pharmacies, etc. and other data may serve as a feasible mechanism to confirm proper class entry.

Not discounting the clear benefit to consumers and to defendants if we could calculate each consumer's increased cancer risk resulting from nitrosamine ingestion from VCDs, the Court finds the Third Circuit's ascertainability standard does not and has never required absolute objectivity. Rather, this standard may be met through a scientifically-rigorous-enough methodology that excludes non-members from class entry and identifies through knowable, searchable, accurate, and relatively complete, business records those consumers who ingested contaminated VCDs in a known amount for a known time. Ascertainability here of putative class members rests not only on the fundamental scientific uncertainty of who will get cancer because of VCD ingestion but also on the wealth of scientifically rigorous, statistically-based epidemiological data of which individuals do get cancer in the U.S. population.

Put simpler, the LCT calculation can exclude non-members and coupling that to the real-world data of Pharmacies and other entities as well as with reliable epidemiological data relating to cancer incidence in the U.S. population can and does fashion a feasible mechanism for identifying members in a statistically appropriate and sufficiently accurate manner.

In addition, Wholesalers aver that since they cannot be associated directly with the class members, they should be relieved of liability for medical monitoring costs. Their argument is that, it is only through linking specific VCD Lot Numbers to consumers' prescriptions that liability can be attributable to a specific Wholesaler. Since Lot Number information linking a mfr's API to a Wholesaler' purchases and then to Pharmacies' sales is unavailable, the Court should exclude Wholesalers from liability.

This argument is similar to the Wholesalers' lack of privity argument made in opposition to their liability for breach of warranty claims. The Court understands from some reports of plaintiffs' experts that there is a pathway to identify some of those Wholesaler to consumer links, even if imperfectly. Again, the ascertainability standard is not perfect member identification but a scientifically rigorous methodology that excludes non-members and includes most members with a sufficient degree of confidence.

Moreover, even if there is no way to link a specific VCD prescription to an individual Wholesaler, from the larger view, there were no U.S. consumers whose VCDs were distributed by entities other than Wholesaler defendants. Even though it may be difficult and even impossible to link which Wholesaler's VCDs were ingested by which consumer, it is certainly knowable that collectively the Wholesaler defendants here put contaminated VCDs into the U.S. drug supply chain. It is therefore feasibly ascertainable that medical monitoring damages of putative class members are attributable to the

distribution efforts of all Wholesalers collectively, for which they may bear group liability. Since such group liability is a determination for a factfinder, the Court does not relieve Wholesalers for liability to this MedMon class.

The Court finds the ascertainability requirement met.

5.7 SUMMARY AND MedMon SUBCLASSES

Having found all *Rule 23(a)* and *(b)(3)* requirements have been met, the Court certifies this *Rule 23(b)(3)* class with the subclasses the Court has confirmed in Table 7.

Table 7: Summary of Incorrect Medical Monitoring Classes and Subclasses and Required Corrections to Plaintiffs' Proposed Subclasses

Rule 23(b)(3) **IND Medical Monitoring Class** **(Listed in Defendants' Appendix A, ECF Doc. 2012-1, as Group 1)**	**Incorrectly Included Jurisdictions In *Rule 23(b)(3)* IND Class**	**Correct MedMon Class / Subclass** **Court compels two Rule 23(b)(2) REM MedMon subclasses:** **1 for jurisdictions REQUIRING Present Physical Injury; and** **1 for those jurisdictions NOT REQUIRING Present Physical Injury**	
		Rule 23(b)(2) **REM Subclass 1:** **Physical Injury Required**	***Rule 23(b)(3)*** **REM Subclass 2:** **Physical Injury NOT REQUIRED**
	IL: MedMon allowed only as remedy; Exclude from ***23(b)(3) IND*** **Class**	Present Physical Injury Required; Include in this Subclass	
	IA: MedMon allowed only as remedy; Exclude from ***23(b)(3) IND*** **Class**	Present Physical Injury Required; Include in this Subclass	
	MO: MedMon allowed only as remedy; Exclude from ***23(b)(3) IND*** **Class**		Include in this Subclass
	NV: MedMon allowed only as remedy; Exclude from ***23(b)(3) IND*** **Class**		Include in this Subclass
	NY: MedMon allowed only as remedy; Exclude from ***23(b)(3) IND*** **Class**		Include in this Subclass
	OR: MedMon allowed only as remedy; Exclude from ***23(b)(3) IND*** **Class** MM	Present Physical Injury Required; Include in this Subclass	

	RI: MedMon allowed only as remedy; Exclude from ***23(b)(3) IND*** **Class**		Include in this Subclass
Rule 23(b)(2 REM **Medical Monitoring Class** **(Listed in Defendants' Appendix A, ECF Doc. 2012-1, as Group 2)**	**Incorrectly Included Jurisdictions In** ***Rule 23(b)(2)*** **IND Class**	**Correct MedMon Class** **Court's research and Defendants' Appendix A, at ECF Doc. 2012-1 confirms there are no jurisdictions allowing Rule 23(b)(3) IND Medical Monitoring claims, which require present physical injury. Court therefore does NOT compel subdivision of Rule 23(b)(3) IND Class into subclasses**	
	AR: MedMon allowed as independent claim; Move from ***23(b)(2)*** **REM Class**	**Rule 23(b)(3) IND MedMon Class** Include in this Class; Present Physical Injury NOT REQUIRED	
Rule 23(b)(2) **REM Medical Monitoring Class (In Defendants Appendix A, at ECF Doc. 2012-1, this is Group 2)**	**Incorrect Subclass in** ***Rule 23(b)(2)*** **REM MedMon Class**	**Correctly Identified Subclass in** ***Rule 23(b)(2)*** **REM MedMon Class**	
		Rule 23(b)(2) **REM Subclass 1:** **Physical Injury Required**	***Rule 23(b)(3)*** **REM Subclass 2:** **Physical Injury NOT Required**
	CN: Remedy requires present physical injury	Include in this Subclass	
	LA: Remedy requires present physical injury	Include in this Subclass	
	MI: Remedy requires present physical injury	Include in this Subclass	
	NE:	Include in this Subclass	

	Remedy needs present physical injury		
	OK: Remedy needs present physical injury	Include in this Subclass	
Jurisdictions Not Allowing Medical Monitoring	ND and NC	These jurisdictions must be removed from either MedMon class.	
Jurisdictions Allowing BOTH Medical Monitoring Classes (these jurisdictions do not require present physical injury in either class)	CA and DC	Both jurisdictions allow both medical monitoring claims as an independent claim and as a remedy.	

6.0 MOTIONS TO PRECLUDE REPORTS OF CLASS CERTIFICATION EXPERTS

6.1 DEFENDANTS' ECONOMIC LOSS EXPERTS

Table 8 shows that defendants filed 17 Class Certification Expert Reports, eight of which were unopposed[55] and therefore unreviewed here and not precluded at this stage. Below are the Court's decisions regarding the parties' motion to oppose their opponents' class certification experts.

Table 8: Motions to Preclude Reports of Defendants' Class Certification Experts

Defendants' Class Certification Expert	ECF No. / (Exhibit No.) of Defendants' Expert's Report	Opposed?
Timothy Anderson, MS, MBA	2009 (197)	No
Steven Baertschi, PhD	2009 (204)	No
Karla Ballman , PhD, Fellow: Am.. Soc. Clin. Oncology	2009 (200)	No
David Chan, MD, PhD	2009 (190)	No
Lewis Chodosh, MD, PhD	2009 (202)	No
John Flack, MD, M.P.H.	2009 (203)	No
Ursina Teitelbaum, MD	2009 (201)	No
Roger Williams, MD	2009 (198)	No
		Opposed? / ECF No. of Plaintiffs' Motion to Preclude
Michael Bottorff, PharmD	2009 (189)	Yes / 2043
David Chesney, MSJ	2009 (194)	Yes / 2038
Jason Clevenger, PhD	2029 (8)	Yes / 2047
Punam Keller, PhD	2009 (191)	Yes / 2041
Timothy Kosty, RPh, MBA	2009 (192)	Yes / 2048
William Lambert, PhD	2009 (195)	Yes / 2044
Mark Robbins, PhD, JD	2009 (199)	Yes / 2045
Eric Sheinin, PhD	2009 (106)	Yes / 2036
Lauren Stiroh, PhD	2009 (193)	Yes / 2046

Michael Bottorff, PharmD

Plaintiffs' Motion to Strike (ECF. No. 2043) New and Altered Causation Testimony in Dr. Bottorff's Class Certification Report (ECF No. 2084, Exh. 2) is **GRANTED.** This Report relates to and expands on testimony in Dr. Bottorff's Causation Report, but is neither fit nor relevant to plaintiffs' proposed class certifications. More importantly, the following three opinions in Dr. Bottorff's Class Certification Report are an improper expansion of his Causation Report and have not been considered in the

[55] Plaintiffs reserve the right to oppose at a later time.

the Court's class certification determinations *supra*:

1) "Oral doses at the levels detected in the generic valsartan at issue in this litigation are metabolized in the liver almost completely, **preventing** exposure to other tissues and organs" (Bottorff Class Certification Report at 48:761-762);
2) "NDMA/NDEA in valsartan **will not reach systemic circulation**" (Bottorff Class Certification Report at 47: 779); and
3) "DNA repair mechanisms in humans can be as much as 10 times higher than that in rats, indicating a more active DNA repair in humans compared to rats" (Bottorff Class Cert. Report at 52:830-831).

[emphasis added]

David Chesney, BA, Master of Science in Jurisprudence

Plaintiffs' Motion to Preclude (ECF No. 2038) the Class Certification Report of David Chesney, MSJ, is **GRANTED in part and DENIED in part.** Even though Mr. Chesney's Report has very little fit, i.e., relevance, to certifying plaintiff's proposed classes because it reads like expert testimony rebutting liability claims, the Court has not precluded it in its entirety.

Mr. Chesney's Report states a single, formal opinion at pg. 5, limited to the conduct of defendant mfr Zhejiang Huahai Pharmaceuticals, Ltd., ["ZHP"]:

"ZHP has a predominately good regulatory inspection with the FDA, and despite certain issues that have arisen, the firm has done exactly what FDA expected and at times requested of them."

Mr. Chesney's Report, from pp: 25-46, offers only testimony about ZHP's compliance, or lack thereof , with FDA current Good Manufacturing Practices and arises from Mr. Chesney's reviews of certain FDA Inspection Reports of ZHP's API manufacturing sites. Even though Mr. Chesney does not relate this opinion or any other discussion in his Report to class certification, the Court has considered Mr. Chesney's specific testimony on pg. 5 of his Report, which directly concerns ZHP's compliance with FDA cGMPs.

The Court's decision rests on Mr. Chesney's assertion that he had actually reviewed ZHP documents, a minimalist indication of opinion reliability. The Court recognizes that Mr. Chesney has not expressly included or discussed negative FDA Inspection Reports of ZHP's API manufacturing sites, which would have balanced the Court's opinion as to the overall reliability of this Report. The Court has not considered Mr. Chesney's opinions or discussion about any other subject matter in his Report.

Jason Clevenger, PhD

Plaintiffs' Motion to Preclude (ECF No. 2047) the Class Certification Expert Report of Jason Clevenger, PhD, is **GRANTED**. Plaintiffs quote from Dr. Clevenger's Report, which offers 2 main opinions, especially regarding Aurobindo's contaminated VCDs:

1) There is "no evidence that the rate / extent of the bioavailability of contaminated valsartan differs from that of the reference listed drug (RLD)." ECF No. 2047-1, at 6. Further, plaintiffs state, Dr. Clevenger opines that recalled Aurobindo VCD products remained bioequivalent even with low levels of NDEA or NDMA. *Id*., at 8.

2) Using higher temperatures to make the Aurobindo finished drug product likely resulted in the volatilization of nitrosamines in the corresponding batches of the API. Dr. Clevenger opines this shows that Aurobindo finished drug batches generally had lower nitrosamine levels than corresponding API batches. *Ibid.*

Dr. Clevenger's opinions fit, i.e., have relevance, to both of plaintiffs' Economic Loss classes, by relating to plaintiffs' theory of economic loss, namely, that the contaminated VCDs, by virtue of their contamination, had no economic value. But his opinions rest on deficient scientific methodology.

Regarding opinion (1), the basis for this was Dr. Clevenger's reading and interpretation of the compendial tests and acceptance criteria in United States Pharmacopeia ["USP"] monographs for valsartan. Having found that no valsartan USP monographs specifically dictate that valsartan API must be tested for nitrosamine impurities, Dr. Clevenger concluded the absence of any mention of nitrosamines in valsartan USP monographs must mean logically that the VCDs at issue are the same as the identical compendial standard of "identity, strength, quality, and purity" of the RLD. Dr. Clevenger went no further than to interpret "the absence of mention" in valsartan USP monographs was an affirmative, positive attribute of valsartan. Dr. Clevenger did not pursue what else the USP might advise about nitrosamine contaminants, even if that advice were not specifically directed at valsartan drug products. The Court sees that the USP website provides such guidance. Dr. Clevenger's one-eye-shut approach is not a scientifically valid methodology. Constituting neither proper scientific deduction, nor inductive research, nor testing to conclusion, nor full scientific literature review, Dr. Clevenger's approach—to rely on an untested lack of evidence to aver the presence of a physical identicality—is sheer sophistry. And to the point, to opine that the absence of evidence demonstrates the presence of a physical property without checking other relevant information and data is a well-known error in logic and belies a reliable method.

Dr. Clevenger's opinion (2) relies solely on his interpretation of Aurobindo's own, initial test results that show the manufacture of finished dose products at elevated temperatures reduced the concentration of nitrosamines, and particularly NDEA, in the finished dose when compared with the

API by about 70%. These results were not replicated by a subsequent test done by Aurobindo or by a separate test done by the FDA. But, Dr. Clevenger's methodology did not include a comparison of Aurobindo's initial test results either with Aurobindo's second results or with the FDA subsequent test results. For this reason, Dr. Clevenger's opinion declaring lower nitrosamine levels in the relevant Aurobindo's FD batches compared to those levels in Aurobindo's relevant API batches is based on skewed results and not methodologically reliable.

Accordingly, Dr. Clevenger's opinions in his Class Certification Report have been precluded.

Punam Keller, PhD

Plaintiffs' Motion to Preclude (ECF No. 2041) the Class Certification Report of Punam Keller, PhD, is **GRANTED IN PART AND DENIED IN PART**. Dr. Keller's Report relates generally to plaintiffs' theory of economic loss for both Economic Loss classes and, more specifically, criticizes the assertions of plaintiffs' economics expert Dr. Rena Conti who argues that the VCDs were worthless from an economics standpoint.[56]

Dr. Keller's opinions important for this discussion include:

1) From consumer market research literature, it is known that consumers often "value" a drug from a multi-dimensional perspective that weighs multiple features (risks and benefits) variously rather than from a binary (positive or negative) assessment of one feature. Dr. Keller's opinion is straightforward: Based on this literature, it is reasonable to expect that economic loss class members would have had a more nuanced valuing strategy for the VCDs than Dr. Conti's worthlessness theory. However, Dr. Keller's opinion is not based on either her own or others' actual consumer market research on VCD consumer's perceptions of VCDs. Rather, Dr. Keller extrapolates from general consumer market research principles as to the possible perceptions of VCD value by economic loss class members.
2) Since consumers paid for VCDs before they were recalled, consumer's valuation of the VCDs must be done retrospectively to consider consumer's value of the VCDs at the time of their purchase. Thus, Dr. Keller's opinion is that relevant consumer market research should be done of consumer's perspectives as to the worth of VCDs, **when consumers knew they were contaminated.** What is wanted is a reliable gauge of how consumers' regarded the value of their VCDs knowing they were recalled for containing a probable carcinogen. However, Dr. Keller appears rather optimistic that a

[56] Dr. Conti's assertions include: If the nitrosamine contamination of VCDs had been known at the time of their sale, the VCDs would have already been recalled and could not have been offered for sale. Consequently, the VCDs would have had had no supply curve and were therefore economically worthless from the time of their contamination. Sales occurred only because the contamination was unknown, not because there was a demonstrated supply curve for the VCDs.

competent market research design would accurately track consumers' perceptions of the value of their CONTAMINATED VCDs. Her opinion about the value of such research is again only her say-so, not a tested hypothesis.

3) Dr. Conti's analysis that VCDs had no economic value—which depends on the fact that VCDs could not have been sold if the nitrosamine contamination were known—is too simplistic and ignores consumers' likely more nuanced valuation of the VCDs.

As a PhD in Marketing, Dr. Keller is qualified to opine on real-world, marketing analyses of consumers' valuation of the VCDs at the time of purchase. She is not qualified to opine on Dr. Conti's economic theory of worthlessness because Dr. Keller is not an economist. The implicit, unspoken supposition in Dr. Keller's opinions is that consumers who needed VCDs to control their blood pressure could have valued the therapeutic effect of their VCDs over the potential cancer risk of taking such genotoxically contaminated drugs. And, such "valuation" could have made their VCDs at least partially economically valuable on the day of purchase.

However, Dr. Keller's Report, especially, at pp. 30 to 45, tries to demonstrate such "could-have" consumer "valuation" without any real-world data, that is, without her own or others' actual consumer surveys, and therefore lacks any, let alone acceptable, scientific methodology. In essence, Dr. Keller's methodology comprises her description of a list of considerations, culled from her understanding of the accepted wisdom in marketing literature, that consumers GENERALLY might have applied in valuing their VCDs on the day of purchase, had they known of the nitrosamine contamination. Inasmuch as consumers did not know of the contamination before recalls, Dr. Keller's extrapolation from the marketing literature has no reproducibility or indeed actual real world referents, unless and until she tests her hypotheses. Her opinions are just her projections as to consumers' considerations, untested and irreproducible. They arise from her assumptions about what factors she would expect consumers to have relied on in valuing their VCDs based on her application of the health care marketing literature. Simply, Dr. Keller asserts a generalized consumer "valuation" without any confirmable results from a real-world marketing survey, her opinion is akin to an "I think so" statement.

Applying tested scientific principles, obtained from a fully fleshed out scientific literature search, to current fact situations can result in predictable, reproducible results and is generally accepted methodology under *FRE 702*. Such an application requires a search query that predicts and finds a sample of scientifically accepted principles in that field, which gives at least an aura of accuracy.

Pointedly, there are several key deficiencies in Dr. Keller's methodology. First, she does not detail her literature search query to show she has conducted a sufficient literature search, but states scientific principles (she presumably is familiar with) and applies them without proof of their representativeness from the relevant body of marketing literature. Another is that she cites no contradictory literature,

principles, estimates, or critiques of the accuracy of her presentiments. Such contradiction can actually prove the accepted principle. Since acceptable scientific methodology does not rest on an expert's say-so, and since Dr. Keller's methodology is only her say-so, Dr. Keller's opinions on pages 30 to 45 in her Class Certification Report have been precluded. Her opinions regarding scholarly literature on consumer health decision-making discussed in pages 1-29 of her Report have been considered but only to the extent that this testimony relates to actual consumer surveys and real world consumer research.

Timothy Kosty, RPh, MBA

Plaintiffs' Motion to Preclude (ECF No. 2048) the Class Certification Report of Timothy Kosty, RPh, MBA, is **GRANTED IN PART AND DENIED IN PART**.

Mr. Kosty's Class Certification Report does two things:

1) From pp. 15-48, it provides background on the workings, processes, and procedures of the pharmaceutical industry and in particular how and where Pharmacy Benefit Managers ("PBMs") fit into the U.S. drug supply chain. Mr. Kosty was expressly asked to explain the factors and practices in the U.S. drug industry, which affect the costs of drugs to consumers and TPPs.

2) From pp: 49-99, his Report refutes three of plaintiffs' class certification experts' reports: Laura Craft's Report on an acceptable methodology for identifying proposed economic class members and on the amount paid for the VCDs; Dr. Rena Conti's Report on valuation of economic losses by consumers and TPPs; and Dr. Kaliopi Panagos's Report on the use of the Orange Book by the drug industry.

Mr. Kosty's qualifications based on his 38 years of experience in the pharmacy business, mainly as a consultant to the pharmaceutical industry, support his exposition at pp. 15-48 of his Report of the workings of the pharmaceutical industry. This exposition has fit, i.e., relevant, to the certification of plaintiffs' proposed economic classes, especially to the *Rule 23(b)(3)* ascertainability requirement of all three classes as well as to general considerations of loss experienced by the Economic Loss classes.

However, Mr. Kosty's refutation of the opinions of plaintiffs' experts, Craft, Conti, and Panagos, lacks even a semi-rigorous methodology. The "methodology" of His Report comprises solely his assertions on how difficult it will be to ascertain the relevant classes and how complex and "individualized" the acquisition and/or calculation and/or identification of class members will be and how generally inadequate plaintiffs' use of certain data is to calculate the loss of economic loss class members' losses. Mr. Kosty's testimony tries to take the place of this Court as arbiter of whether the ascertainability requirement of *Rule 23(b)(3)* has been met. Especially as regards his refutation of Ms. Craft's Report, Mr. Kosty repeats over and over how using pharmacy records of consumer transactions,

coupled with the PBMs records, coupled with the TPPs records will require complex, difficult, and complicated data tracking across dissimilar systems to identify class members. However, he seems wholly unaware that complex data tracking of individual class members or of an aggregate class is not legally sufficient to nullify ascertainability, as discussed herein in Sections 5.6.2.2, 4.3.3, and especially in 3.3.3.

In refuting Dr. Conti's proposition that the recalled VCDs were economically worthless, Mr. Kosty asserts, without more, that consumers themselves as well as regulatory agencies would not have regarded the VCDs worthless. He cites no relevant literature or consumer market research for support. Mr. Kosty further asserts Dr. Conti's calculation of losses by consumers and TPPs would be complex, difficult, and predictive at best, but certainly not definitive.

Plus, Mr. Kosty points out that Dr. Conti did not consider that consumers may have adopted alternative hypertensive medication. But, he does not appreciate the effect of his alternative-medication argument: that consumer adoption of a hypertensive substitute reinforces Dr. Conti's hypothesis that the VCDs were economically worthless, which may implicate that the cost of a possibly more expensive hypertensive substitute could add to consumers' and TPPs' economic losses. Mr. Kosty, while certainly experienced in the workings of the U.S. drug industry, holds no expert qualifications in the economics, for valuing either the market forces of drug sales or supply chain flow.

In addition, Mr. Kosty states that Dr. Panagos is incorrect when she asserts that the FDA's Orange Book acts as a warranty to consumers and their insurers. Dr. Kosty asserts without more that the drug industry would not have regarded the Orange Book as a warranty that generic drugs are the equivalent of all of the RLD's biological and chemical features Regardless of the correctness of Dr. Panagos' opinion about the drug industry's perception of the Orange Book as a warranty of the substantial equivalence of generic drugs, Mr. Kosty's refutation of the drug industry's "perceptions" needed more reliable support than his mere disagreement.

In sum, Mr. Kosty's Report lacks scientifically reliable methodology and/or necessary expert qualifications in refuting the Class Certification Reports of plaintiffs' experts, Laura Craft, Dr. Rena Conti, and of Dr. Kaliopi Panagos.

Accordingly, Mr. Kosty's opinions in pages 49-99 in his Report have been precluded. His discussion on the workings of the U.S. pharmaceutical industry in pages 15-48 of his Report has been considered.

William Lambert, PhD

Plaintiffs' Motion to Preclude (ECF No. 2044) the Class Certification Report of William J. Lambert, PhD is **GRANTED IN PART AND DENIED IN PART.**

As a PhD of Pharmaceutics and with many years experience assessing and developing drug delivery processes, Dr. Lambert has expert knowledge of drug manufacturing, including knowledge of cGMPs, and especially of those relating to cleaning verification and validation of manufacturing equipment. He is qualified to opine generally on the manufacturing practices and processes in the pharmaceutical industry and as to the FDA's inspection of them. As an expert engaged by the API mfr Aurobindo, Dr. Lambert more specifically opines on the reasonableness of Aurobindo's behavior in adhering to the general practices and processes in the pharmaceutical industry as well as to industry-wide responses to FDA demands and inspections. In essence, Dr. Lambert is opining on the close fit between Aurobindo's behavior in verifying manufacturing equipment and responding to the FDA when compared to the general conduct of pharmaceutical manufacturers and the culture of the pharmaceutical industry.

Dr. Lambert's opinions rely on a list of unpreciséd Aurobindo documents enumerated only by Bates numbers, which the Court neither has nor can peruse. Neither has he delineated his search query that chose these documents nor described generally or specifically the reason for their selection. Although a qualified expert, the Court finds Dr. Lambert may have cherry-picked only those Aurobindo documents that push his opinions on Aurobindo's conduct to favorable. That alone does not automatically lead to the conclusion that Dr. Lambert's methodology, and therefore his opinions, are scientifically suspect. But neither does it speak to the scientific rigor of his methodology. The lack of meticulousness in Dr. Lambert's scientific methodology has driven the Court to review minutely Dr. Lambert's opinions, which are summarized below.

- Aurobindo VCDs met the USP compendial standard because they were approved generics listed in the Orange Book. They therefore were bioequivalent to their respective RLDs.
- Plaintiffs failed to apply correct standards for bioequivalence and pharmaceutical equivalence.
- Aurobindo's contaminated VCDs did not have altered bioequivalence because of the contamination and were not "worthless".
- Aurobindo reasonably investigated the presence of nitrosamines once they were detected in lots of contaminated API.
- Only 2 lots were above the Limit of Quantitation for NDMA , and both were below the FDA's Acceptable Intake limit.
- Aurobindo had no reason to test specifically for nitrosamines in its API and no reason to use gas chromatography-mass spectrometry or liquid chromatography as testing methods until after the FDA

stated publicly in December 2018 and in January 2019 that these testing methods were the more rigorous.

- Aurobindo had a reasonable risk assessment process in place for detection of nitrosamines in its API. As using recovered solvents is customary in the drug industry and allowed by the FDA, Aurobindo's use of Lantech as a contract manufacturer was appropriate after Aurobindo had reasonably qualified and overseen Lantech.
- The FDA's Orange Book did not set forth or create manufacturer warranties. This opinion points to a legal conclusion and has been precluded.
- In addition to these general opinions, Dr. Lambert's refutes the opinions of plaintiffs' experts Dr. John Quick, Dr. Ron Najafi, and Dr. Kaliopi Panagos.

The following opinions in Dr. Lambert's Class Certification Report have been precluded:

1) Dr. Lambert's opinion about the "worthlessness" of the VCDs, couched in terms of bioequivalence; this is an unqualified economics opinion.
2) Any of Dr. Lambert's opinions that the FDA's Orange Book does or did not set forth or create manufacturer warranties. By excluding these opinions of Dr. Lambert's, the Court is not expressly endorsing that the Orange Book creates manufacturer warranties; rather, the Court finds that Dr. Lambert is not a legal expert qualified to opine on such an issue.
3) Dr. Lambert's opinions that plaintiffs failed to apply correct standards for bioequivalence and pharmaceutical equivalence.
4) Dr. Lambert's opinions at ¶38 of his Class Certification Report.
5) Dr. Lambert's opinions at ¶88 and ¶90 of his Class Certification Report.

All other opinions in his Report have been considered.

Mark Robbins, PhD, JD

Plaintiffs' Motion to Preclude (ECF No. 2045) the Class Certification Report of Mark Robbins, PhD, JD is **DENIED.**

In his Report, Dr. Robbins refutes the opinions of plaintiffs' class certification expert Mr. John Quick as well as disputes plaintiffs' allegations as they relate to Torrent's (finished dose mfr) violation of the FDA's cGMPs, thereby causing the NDMA/NDEA contamination of its VCDs. As a PhD in Pharmacology and a lawyer, with years-long experience as consultant to the pharmaceutical industry, Dr. Robbins is qualified to opine on the subject matter of his Report. Plaintiffs argue that Dr. Robbins' Report is filled with incorrect statements about FDA warning letters and FDA regulatory practice. These are fact questions that the Court does not weigh in a class certification review.

Plaintiffs also assert Dr. Robbins' testimony lacks fit because it does not directly rebut Mr. Quick's expert opinions. While not a direct rebuttal of Mr. Quick's testimony, Dr. Robbins' Report does have fit, that is relevance, to the class certification matters Mr. Quick raised. Mr. Robbins' Report purportedly reviews Torrent and ZHP documents relating to whether industry practice and norms would have motivated Torrent to review ZHPs manufacturing method more thoroughly.

Plaintiffs also argue that Dr. Robbins' Report is methodologically unreliable. Because of the small number of hours he was paid for, the great number of documents his Report reviews, and of Dr. Robbins' deposition testimony admitting to lack of knowledge of certain Torrent personnel and documents, plaintiffs conclude Dr. Robbins cannot have prepared most of his Report and that Dr. Robbins' assistants must have prepared the bulk of it. Thus, the Report is not that of an expert, but of assistants, and plainly unqualified under *FRE 702*.

Defendants counter that plaintiffs' assertion of Dr. Robbin's lack of involvement in his Report goes to the weight of Dr. Robbins' argument, not to its admissibility. The Court agrees. Dr. Robbins' Report identifies which Torrent and ZHP documents were reviewed and thus constitutes the bare minimum of the preponderance of evidence standard that defendants must meet to show reliable method. Further, the Court appreciates that plaintiffs at trial may attack the reliability of authorship, and therefore the weight of Dr. Robbins' opinions, by raising Dr. Robbins' deposition testimony. And for this reason, Dr. Robbins' opinions have been considered.

Eric Sheinin, PhD

Plaintiffs' Motion to Preclude (ECF No. 2036) the Class Certification Report of Eric Sheinin, PhD is **GRANTED IN PART AND DENIED IN PART.**

As a PhD in Medicinal Chemistry and having long experience at the U.S. FDA, Dr. Sheinin is qualified to testify on FDA regulatory practices. Dr. Sheinin's Report is 23 pages long. In the 6 first pages, Dr. Sheinin covers his professional history; in the next 6 pages, he gives an overview of the US regulatory principles relating to drug manufacture without footnote or reference. Dr. Sheinin takes the next page to state simply that API sold in the US is expected to be manufactured under cGMPs described in FDA Guidelines. He does not clarify what those FDA Guidelines state.

Dr. Sheinin then spends pages 13 – 17 of his Report to clarify what other defendants' class certification experts have said: that at the time of the valsartan API contamination, and in particular the API of his client, Mylan, there was no FDA guidance or an FDA Drug Master File that alerted Mylan to the need for testing its API for NDEA. Dr. Sheinin's paragraph 69 states, without cited authority, reference, footnote or endnote, that "a drug substance or drug product is not considered misbranded

or adulterated simply because it contains impurities (even potentially genotoxic impurities.") Dr. Sheinin then asserts that according to FDA public statements, the FDA first learned of the nitrosamine contamination of VCDs on 19 June 2018. Dr. Sheinin implies that, before this date, the FDA neither expected nitrosamine contamination in valsartan nor had developed a method or Guidance for testing for it. He then states that his client, Mylan, had likewise, no knowledge or expectation to test valsartan API for nitrosamines before the FDA developed its gas- and liquid- chromatography tests in late 2018 and early 2019, and that Mylan's knowledge was in line with the received wisdom from the DMF and the US Pharmacopeia. In pages 13-17, Dr. Sheinin avers that it was not until 1 Dec 2021—when the US Pharmacopeia included a titled chapter "Nitrosamine Impurities"—that the first formalized guidance surfaced to drug manufacturers about testing for nitrosamine contamination in their drugs. He seems to be implying that the API mfrs might be somewhat relieved of liability because they could not have known about nitrosamine contamination before the recalls. Even though that implication is a fact question for the factfinder, the Court has considered Dr. Sheinin's opinions on pages 13-17 in his Report.

In the last four pages of his Report, at pp. 19-23, Dr. Sheinin then disputes the opinions of plaintiffs' class certification expert Dr. Ron Najafi that Mylan's VCDs, contaminated with NDEA, were not bioequivalent to the Reference Listed Drug [in the Orange Book]. The thesis of Dr. Sheinin's Report is that, since the FDA analyzed Mylan's ANDA for generic valsartan drug products with reference to the Drug Master File, Mylan's approved and manufactured VCDs contained impurities that did not alter the bioequivalence of the RLD, because the FDA did not expect or consider nitrosamines in generic valsartan. And therefore, Dr. Najafi's opinion that VCDs containing NDMA and NDEA was not the generic equivalent of the RLD patent products is incorrect.

The Court finds Dr. Sheinin's Class Certification Report methodologically unreliable and accordingly has excluded a number of paragraphs in his Report. The unreliability arises from the considerable lack of transparency and a complete lack of methodological clarity in the Report. To wit, Dr. Sheinin nowhere provides a statement of relevance, that is, a reason, a purpose, or a context for his Report, which makes it conceptually impossible to ascertain how his Report "fits" the class certification context. His Report comprises largely "Background", a somewhat veiled attempt at opining on liability, and a purported refutation of Dr. Najafi's Class Certification Report; it has little to no bearing on class certification issues. Dr. Sheinin does not detail what documents he has reviewed, why he reviewed them, what his search query was, and why he excluded other documents: in short, he stated no method.

The Court has reviewed in detail Dr. Sheinin's Class Certification Report and has excluded the following paragraphs: paragraph 69, and paragraphs 79 to 102, because they either draw a legal conclusion or expound an opinion unsupported by any cited or referenced documents that Dr. Sheinin

declares he has reviewed. Hence, the Court cannot know what reviewed documents, if any, contribute to and support his assertions.

Moreover, paragraphs 25 to 68, and paragraphs 70-78 in Dr. Sheinin's Report have been considered but only as Background information, not as reliable expert opinion on class certification issues.

Lauren Stiroh, PhD

Plaintiffs' Motion to Preclude (ECF No. 2046) the Class Certification Report of Lauren Stiroh, PhD is **DENIED.** As a PhD in economics, Dr. Stiroh has suitable qualifications for the subject matter of her Report; her opinions relate directly to class certification issues; and she has recounted the materials and the bases in a way that demonstrate reliability in method and thereby support her conclusions.

Her Report is largely a refutation of Dr. Rena Conti's Class Certification Report for plaintiffs. In general, Dr. Stiroh relies on similar data as Dr. Conti to reach the conclusion that economic loss damages to ConEcoLoss and TPPEcoLoss classes cannot be assessed on a class-wide basis using information and methods common to the proposed class because there is no information that is common to the proposed classes or that predominates.

Dr. Stiroh disagrees with Dr. Conti's determination that the sold VCDs were worthless and had zero value at the time of sale. This is so because the VCDs continued to be sold / consumed for a period of time after the recall, thereby demonstrating their therapeutic effectiveness. She asserts economic value is an individualized determination based on multiple factors, not on a simplistic demand-supply chart.

Although the Court has certified *supra* the ConEcoLoss and the TPPEcoLoss classes primarily because of Its finding that common factors predominate throughout these classes, Dr. Stiroh's Class Certification Report disagrees that common factors predominate. Her Report is from a qualified expert, fit for its purpose, and arises from a reliable methodology and nonetheless presents a contradictory opinion, which, because of its reliability, the Court finds important to have considered.

6.2 PLAINTIFFS' ECONOMIC LOSS EXPERTS

Table 9 shows that plaintiffs filed 7 Class Certification Reports, one of which was unopposed[57], therefore unreviewed here, and not precluded.

[57]The Court preserves defendants' right to oppose Laura Craft's Class Certification Report at a later time.

Table 9: Motions to Preclude Reports of Plaintiffs' Class Certification Experts

Class	Plaintiffs' Class Certification Expert	ECF No (Exh No) of Plaintiffs' Expert Report	Opposed ? / ECF No. of Defendants' Motion to Preclude
Both EcoLoss	Laura Craft	1748 (2)	No: Unopposed Directly; Criticized in other Motions to Preclude
Both EcoLoss	Rena Conti, PhD	1748 (1)	Yes / 2037: Wholesalers; Yes / 2040: General Defendants
All 3 classes	Ron Najafi, PhD	1748 (3)	Yes / 2033
Both EcoLoss	John Quick, MBA	1748 (4)	Yes / 2035
TPPEcoLoss	Kaliopi Panagos, PharmD,RPh	1749 (3)	Yes / 2034
MedMon	Edward Kaplan, MD	1750 (5)	Yes / 2024
MedMon	Zirui Song, MD, PhD	1750 (6)	Yes / 2032

Rena Conti, PhD

Defendants' Motions to Preclude (ECF Nos. 2040 ["General Motion"] and 2037 ['Wholesalers Motion"]) the Class Certification Report of Rena Conti, PhD are **DENIED.** As a PhD in the Economics of Health Policy, Dr. Conti is qualified to opine on economic loss in this litigation. Her opinions relate specifically to the amount of loss the Economic Loss classes experienced in paying for VCDs. Dr. Conti's methodology includes the following:

- a review of specific FDA Regulations;
- based on this review, a hypothesis of economic worthlessness, which relies on simple supply and demand curves that show VCDs can only ever be deemed worthless from a classical economics perspective because, had the FDA known of the VCD contamination from the start, it would have recalled the VCDs, thereby making them unsaleable and lacking a supply curve;
- a calculation of loss based on this economic worthlessness theory, and
- a review of available and relevant Iqvia Exponent data to calculate a separate, aggregate loss to both the ConEcoLoss and the TPPEcoLoss classes.

The core of Dr. Conti's worthlessness theory is:

IF a generic drug does not meet EITHER FDA Orange Book standard 3,[58] OR FDA Orange Book standard 5,[59] THEN the generic drug cannot and will not be put into the supply chain. In economic terms, such a drug will be recalled or prohibited from sale, can have no supply curve, and is therefore worthless.

Dr. Conti recognizes that any inactive additives in the generics typically do not affect value, and therefore do not affect drug sales so long as the additives are shown not to affect safety or efficacy of

[58] a drug manufacturer's assurance that its generic drug meets compendial or other applicable standards of strength, quality, purity, and identity.
[59] a drug manufacture's assurance that its generic drug was made in compliance with cGMP regulations.

the proposed generic. Dr. Conti argues that, since both FDA Orange Book standard 3 and standard 5 were not met, the VCDs should not have been sold. Her economic loss model equates the price paid for all VCDs that should not have been placed into the U.S. drug supply chain is the economic loss of consumers and PPs that shared the costs of those VCDs. Simply, the total economic loss of consumers and the TPPs is the combined price each group paid for the VCDs.

Dr. Conti recognizes the Iqvia Exponent data are incomplete and do not track 100% of all VCD drug transactions, but only about 93%. Nonetheless, she avers these data are the gold standard of U.S. drug sales information, which allow her to calculate average drug sales costs—not specific costs paid by specific consumers or TPPs—which thereby gives her an aggregate calculation of total losses of the Economic Loss classes. Moreover, Dr. Conti uses data of drug sales available from Pharmacies, which inform only on amounts paid by consumers and not by TPPs, to refine her calculation of economic losses.

Defendants' General Motion avers Dr. Conti's opinions rest on the highly flawed premise that the VCDs had no value. Defendants aver to the contrary that, since the VCDs were therapeutically effective, they did have value to hypertensive consumers. Further, the General Motion points out that Dr. Conti's methodology for calculating economic loss damages for both classes is flawed because her calculations of loss use only the point-of-sale amounts consumers paid for the VCDs, which miscalculates and actually overstates Pharmacies' profits. They further contend that Dr. Conti's calculation of "average" sales considers neither the Pharmacies' costs of making the drug sales nor any drug rebates that uninsured consumers took advantage of. The point is, these two variables—drug costs and drug discounts—when accounted for, would lower the "average" consumer cost and the overall economic loss. Defendants also argue that Dr. Conti's unjust enrichment damages calculation model is contrary to basic economic principles and legal considerations. That is, her model uses the same computational method for the warranty, fraud, and consumer protection claims as for the unjust enrichment claim. Since the standards of liability for these two different sets of claims differ greatly, her calculation model for unjust enrichment damages is simplistic and does not fit legal reality.

Wholesalers' Motion avers that Dr. Conti's opinion is methodologically unreliable as she does not calculate the Wholesalers' unjust enrichment damages; she just spells out a formula for calculating them. However, Dr. Conti could not get the following data she needed to calculate such damages, especially from Wholesalers, to wit;

- Wholesalers' rebates from valsartan drug manufacturers;
- their reduced costs negotiated with the mfrs and the PBMs (which thereby lower Wholesaler profits);
- Wholesalers' sales agreements with Pharmacies, which again lower Wholesaler profits, etc.

This was because a previous discovery ruling in this MDL several years ago relieved Wholesalers from producing such data. Wholesalers nonetheless argue that, without necessary data to calculate unjust

enrichment damages, Dr. Conti's calculation model renders her opinion as to Wholesalers' unjust enrichment damages useless and unreliable. The Court sees Wholesalers' argument here as akin to the Catch-22 situation for the plaintiffs in *RealPage*, discussed *supra.*

The Pharmacies claim that their data upon which Dr. Conti relied do NOT include their costs for dispensing VCDs to consumers. They therefore aver Dr. Conti's methodology is completely opaque as to how, or even if, she accounted for Pharmacies' dispensing costs in her unjust enrichment calculations. Wholesalers argue Dr. Conti does no more than merely state that she needs other kinds of data, unavailable to her at the time of her Report, to calculate the unjust enrichment damages attributable to Wholesalers. Both Wholesalers and Pharmacies aver Dr. Conti's methodology as to Wholesalers' unjust enrichment damages is merely outlined and undemonstrated.

The general gist of defendants' arguments is that Dr. Conti arrived at her economic theory of VCD worthlessness only by relying on, *ab initio*, plaintiffs' legal allegations of their worthlessness; she then matured that theory by interpreting that defendants' purported noncompliance with cGMPs signaled violation of certain Orange Book regulations, which "demonstrated" the VCDs should not have been sold and were thus worthless. Then, defendants argue, Dr. Conti uses an equation from freshman economics classes— Profits = Revenue – Costs—to calculate the losses realized by the Economic Loss classes and unjust enrichment damages. In particular, Pharmacies contend that Dr. Conti's overly simplified mathematical model does not stop there, but that she then inserts as Revenue into her one-dimensional equation Pharmacies' point of sale ["POS"] data to calculate Pharmacies' Revenue and Profits in an unrealistically simple way.

The Court notes defendants' motions to preclude Dr. Conti's opinions did not oppose directly the arguments relating to Dr. Conti's "worthlessness" theory, but rather assert that her mathematical model for calculating economic loss is overly-simplified and inappropriate. Even though several of defendants' class certification experts have argued Dr. Conti's worthlessness theory is faulty economics, the Court has found that only Lauren Stiroh, PhD qualified as a defendants' expert to dispute this theory.

The Court has considered carefully all of the parties' arguments and concludes that Dr. Conti has set forth a general calculus, i.e. mathematical model, which, although possibly flawed because the data are not available or forthcoming, may reliably support her presumption of the worthlessness of the sold VCDs. The Court notes further that almost all debate in both of defendants' motions concerns the incorrect data Dr. Conti used to arrive at her damages calculations and that defendants appear to conflate Dr. Conti's "worthlessness" theory with her not-fully-fleshed-out mathematical model which uses not fully available data to calculate damages.

The Court also notes defendants' motions did not defeat plaintiffs' arguments that Dr. Conti's "worthlessness" theory has already achieved validation in B*CBS v GlaxoSmithKline*, No. 13-4663, 2019

WL 4751883, at *8-9 (E.D. Pa. 30 Sep 2019). The B*CBS* Court found that not only was Dr. Conti's theory of "worthlessness" appropriate but also her methodology in adopting and justifying the theory was reliable. This Court has also found that the cases defendants have cited—I*n re Rezulin Prods. Liab. Litig*., 210 FRD 61, 68-69 (S.D.N.Y. 2002) [*concerning* standing and class certification] and *Shahinian v Kimberly Clark Corp*, No. Civ 14-8390 DMG (PLAx), 2017 WL 11595343, at *11 (C.D. Cal. 7 Mar 2017) [*concerning* a dental device and not a drug containing a dangerous additive]—are not on point.

At class certification stage, the methodology of an expert need not be perfect or even legally correct. In *Rule 702* determinations, the Court does not take the place of the factfinder to adjudicate the fundamental issues for trial but decides if those issues have been presented in a scientifically reliable way. Here, the fundamental issues are: Dr. Conti's theory of economic worthlessness of the contaminated VCDs, which drives her specific equations for calculating economic loss. This is directly opposed by defendants' experts arguments that VCDs, although contaminated, did lower consumers' high blood pressure, thereby providing therapeutic value, which belies economic worthlessness.

The Court must, to every extent possible and necessary, refrain from any preliminary judgment as to the legal correctness of any expert's opinions and leave that for the factfinder. However, the Court must thoroughly review the methodology of an expert and find it to have scientifically reliable underpinnings. The Court so finds Dr. Conti's methodology to have sufficient scientifically reliable underpinnings and makes no statement here as to its legal propriety. Accordingly, the Court has considered Dr. Conti's opinions.

Ron Najafi, PhD

Defendants' Motion to Preclude (ECF No. 2033) the Class Certification Report of Ron Najafi, PhD is **GRANTED.** Dr. Najafi, Ph.D. in Organic Chemistry, is CEO of an FDA registered and inspected Contract Research Laboratory that helps drug companies follow regulatory guidance and comply with current Good Manufacturing Practices ["cGMPs"] / Good Laboratory Practices ["GLPs"] in their development of new drug products. Dr. Najafi therefore holds himself as an expert on drug formulations. His Class Certification Report focuses on whether VCDs containing NDMA or NDEA were the same or not as the branded Diovan® or Exforge® (i.e. patented) Reference Listed Drug products upon which the generic manufacturers' ANDAs were based. In a nutshell, Dr. Najafi avers the VCDs are not the same drug products as the Reference Listed Drug in the Orange Book because NDMA and NDEA are carcinogenic and should not be or have been present in any drugs put into the U.S. drug supply chain.

To be clear, several parties' class certification experts—for defendants: Dr. Clevenger, Dr.

Keller, Mr. Kosty, and Dr. Lambert; for plaintiffs, Dr. Najafi, and Dr. Panagos—raise the issue of "bioequivalence", "therapeutic equivalence", or "pharmaceutical equivalence". None expressly states how their opinions on the VCDs' bioequivalence or lack of it relate to the certification of plaintiffs' proposed classes.

Nonetheless, the Court appreciates why the parties' experts contest this issue. These opinions relate directly to Dr. Conti's theory that the VCDs are economically worthless because of the nitrosamine contamination. As discussed *supra*, the important bridging argument in Dr. Conti's theory is, Had the FDA known of the nitrosamine contamination, the VCDs could not have been sold, and would have had no supply curve. In practical terms the "no supply curve" theory is borne out only after the FDA issued recalls for each VCD, which effectively ended the U.S. market supply of that particular VCD.

The Reports of Dr. Clevenger, Dr. Keller, Mr. Kosty, Dr. Lambert, Dr. Najafi, and Dr. Panagos purport to opine on which model is appropriate for calculating damages of the Economic Loss classes. Defendants' experts assert the VCDs were "bioequivalent" or "therapeutically equivalent" or "pharmaceutically equivalent" to the Reference Listed Drugs, which compels a reduction of economic loss damages for plaintiffs' claims of implied breach of warranty, fraud, and unjust enrichment. Defendants' supporting premise is that, since the VCDs worked as intended, even if nitrosamine-contaminated, plaintiffs got the drug they paid for, and no breach of warranty, fraud, or unjust enrichment can have occurred. To contrast, the essence of plaintiffs' theory of economic loss is a prediction of what the FDA would have done had it known about the contamination earlier: stop VCD sales; and the essence of defendants' thesis is the assertion of what consumers did while the recalls were occurring: continue to take VCDs.

The problem for the Court with these expert opinions regarding "bioequivalence", "therapeutic value", and "pharmaceutical value" is that no expert has conducted actual consumer or physician surveys to confirm an "equivalence" perception. The impasse in defining "bioequivalence", etc. arises from the differing interpretations by defendants' and plaintiffs' experts' of the language of the Drug Master File, the Reference Listed Drug, the U.S. Pharmacopeia, etc. Many of these expert interpretations rise to little more than "story". There is no direct evidence of consumers' preferences or practices, other than news media reports of physicians' and consumers' confusion and alarm over the only two outcomes available upon VCD recall:

1) stop taking the VCDs, which could have caused more immediate, dangerous sequelae, as heart failure and stroke, and/or

2) switching to another, less effective, hypertensive substitute, which can have engendered its own set of alternative damages.

Nowhere do the experts' Reports consider the fundamental dilemma faced by the American Medical Association and U.S. consumers: that they were between a rock and a hard place because of the VCD recalls; and they may have made decisions not based on typical consumer-oriented considerations because the recalls removed lickety-split vast amounts of the most prescribed blood pressure and heart failure medicine from the U.S. market and induced an accompanying uncertainty in consumers and physicians alike as to the effectiveness of drug substitutes for a very large swath of the American public.[60]

In their Reports, defendants' and plaintiffs' experts talk "past each other" and use different terms when defining "bioequivalence", "therapeutic equivalence", or "pharmaceutical equivalence". But, importantly, the dispute among various experts as to the meaning of bioequivalence, pharmaceutical equivalence, therapeutic value, worthlessness, etc. may be a central issue for, and will have a decisive effect on, the calculation of economic loss damages. Therefore, the Court finds the essential dispute between economic worthlessness vs "bioequivalence" must be put before the factfinder so that it can weigh and decide on these terms that relate to the overarching question, what damages are plaintiffs owed? Thus, the subject matter of Dr. Najafi's opinions, about what is bioequivalence, wades too far into the factfinder's domain and is not relevant to the class certification issue at hand. Accordingly, the Court has precluded the Class Certification Report of Dr. Ron Najafi.

John Quick, MBA

Defendants' motion to Preclude (ECF No.2035) the Class Certification Report of John Quick, MBA, is **GRANTED IN PART AND DENIED IN PART.** Mr. Quick was asked to evaluate whether certain behavior by API and FD mfrs complied with the FDCA and the cGMPs promulgated in the FDA Guidances and whether a mfrs noncompliance negatively affected each VCD equally. As Mr. Quick's Report concerns generally the certification of the Economic Loss classes and specifically plaintiffs' assertion that defendants' non-compliance with cGMPs supports a finding of *Rule 23(b)(2)* predominance in those classes, it is fit for its purpose.

Mr. Quick's qualifications arise largely from his seventeen years as Vice President of Regulatory and Quality operations for an international S&P-500 pharmaceutical company. His methodology is to review a body of materials[61] and opine on how a mfr's conduct and possible noncompliance with

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[60] Aaron Gould Sheinin, Updated 23 September 2019, *Valsartan, Losartan & Other BP Med Recalls 2018-19*, WEBMD, available at https://www.webmd.com/hypertension-high-blood-pressure/valsartan-losatran-bp-med-recalls-2018-19, last accessed 11 Jan 2023; Patrice Wendling, 28 March 2019, *Continuing ARB Recalls Shake Up Hypertension, HF Care*, MEDSCAPE, available at https://www.medscape.com/viewarticle/911055?reg=1, last accessed 11 Jan 23 (requires free registration) .

[61] **Discovery Produced Documents**: ZHP01427917; ZHP00000161 (and translation provided by Counsel); ZHP00000417; ZHP01427950; ZHP01748896; ZHP02630924; ZHP02118072; ZHP02118712; ZHP00912962; ZHP00079913.

cGMPs in general had a systemic impact on its manufacture of VCDs. Mr. Quick analyzes the information he gleans from these materials (the subject matter of which is at least nominally identifiable from their titles and which the Court of course is not privy to) to opine on whether a mfr had serious, systemic issues related to their corporate quality assurance ["QA"] operations. Although Mr. Quick asserts he does not opine on whether these corporate QA failings were the ultimate reason why the VCDs contained NDMA / NDEA, he does conclude from the reviewed documents that each of the mfrs' QA deficiencies showed high level, corporate QA shortcomings. That is, from a high-level, corporate view, each deficiency would have impacted each of the mfrs' VCDs equally and similarly. In practical terms, Mr. Quick's analyzes the material listed in fn. 61 to see if corporate QA behavior worked to promote in the same way the possible contamination of all the mfr's VCDs.

Acknowledging defendants' contentions that Mr. Quick quite possibly cherry-picked the documents he reviewed, the Court also appreciates that his methodology is not rendered unreliable because he did not systematically review "discovered documents" because his is not a causation opinion. The Court acknowledges that a completely balanced review of both the "positive" and the "negative" documents would have been the most reliable methodology. But here, there is insufficient

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PRINSTON00463786; PRINSTON00368123;

TORRENT-MDL2875-00005036; TORRENT-MDL2875-00000149; TORRENT-MDL2875-00003958; TORRENT-MDL2875-00131251; TORRENT-MDL2875-00004186; TORRENT-MDL2875-00072520; TORRENT-MDL2875-00291311; TORRENT-MDL2875-00433346

MYLAN-MDL2875-00421388; MYLAN-MDL2875-00421389; Glover Deposition Exhibit-56; Glover Deposition Exhibit 57; MYLAN-MDL2875-00257214; MYLAN-MDL2875-00257215; MYLAN-MDL2875-00708138;

APL-MDL2875-0964965; APL-MDL2875-0391332; APL-MDL 2875-0504366

TEVA-MDL-00158603; TEVA-MDL2875-00684220; TEVA-MDL2875-00259905; TEVA-MDL2875-00259910; TEVA-MDL2875-00020279; TEVA-MDL2875-00791611; TEVA-MDL2875-00549883; TEVA-MDL2875-00049024; TEVA-MDL2875-00320639; TEVA-MDL2875-0399168; TEVA-MDL2875-00118147; TEVA-MDL2875-00415117; TEVA-MDL2875-00247059; TEVA-MDL2875-00318831

HLL446173; HETERO_USA000151204

Depositions
Jucai Ge (ZHP); Min Li (ZHP); Remonda Gergis (ZHP); Eric Tsai (ZHP); Minli Zhang (ZHP);
Derek Glover (Mylan); Daniel Snider (Mylan); Antonyraj Gomas (Mylan)
Daniel Bareto (Teva); Anthony Binsol (Teva); Pan Lin Deposition (Teva); Narendra Vadsola (Teva)
Sushil Jaiswal Deposition (Torrent); Dawn Chitty Deposition (Torrent);
Ambati Rama Mohana Rao (Aurobindo); Sanjay Singh (Aurobindo)

Publicly Available Documents
FDA Compliance Program Guidance Manual 7356.002F, September 11, 2015
FDA Power Point Presentation by Robert C. Horan, New York District, "FDA cGMP Inspection, Peking University 2005"
FDA Guidance Q10 "Quality Systems Approach to Pharmaceutical CGP Regulations," September 2006
FDA Guidance Q10, "Pharmaceutical Quality System 3
FDA Guidance "Contract Manufacturing Arrangements for Drugs: Quality Agreements," November 2016.
FDA Guidance, "Control of Nitrosamine Impurities in Human Drugs," Feb 2021
FDA Compliance Program Guidance Manual, API Process Inspection, September 11, 2015, page 4
FDA Presentation, "FDA's Pre-Approval Inspection (PAI) Program & How to prepare for a successful outcome," Denise DiGlulio, FDA Facility Reviewer, Office of Process & Facilities, Fall 2015.
FDA Presentation, "The Pharmaceutical Quality System (PQS)," Robert Iser, FDA Office of Process & Facilities/OPQ/CDER, July 15, 2015.
FDA Warning Letter, Akorn, Inc. June 13, 2019, and US Pharmaceuticals, Inc. June 6, 2019.

detail from both parties as to how these documents were or not selectively chosen. And at trial, defendants can certainly present their "positive behavior" documents showing their clients' compliance with cGMPs.

The Court finds Mr. Quick's methodology generally reliable because of his extensive, practical experience in identifying and correcting corporate QA norms likely to support a corporate-wide tendency towards noncompliant cGMP behavior. But as with Dr. Lambert's Report, the Court finds Mr. Quick's methodology not entirely rigorous and has reviewed Mr. Quick's Report minutely, but has not reported on it here.

However, on pp. 6-7 of his Report, Mr. Quick opines on the meaning of "adulterated" and "misbranded" as presented in the FDCA and corresponding U.S. codes and regulations. An interpretation of these terms is more legally nuanced than Mr. Quick is qualified to opine on. Therefore, Mr. Quick's opinions on pp. 6-7 of his Report regarding his interpretations of the terms "adulterated" and "misbranded" and whether the VCDs were adulterated or misbranded have been precluded.

However, the rest of Mr. Quick's opinions is his Report have been considered.

Kaliopi Panagos, PharmD, RPh

Defendants' motion to preclude (ECF No. 2034) the Class Certification Report of Kaliopi Panagos, PharmD and RPh, is **GRANTED IN PART AND DENIED IN PART.** Dr. Panagos's Report is 10 pages long, the first five pages of which are descriptions of the various players in the U.S. drug supply chain, such as TPPs, Pharmacy Benefit Managers, the Orange Book, etc. On pages 5-6, Dr Panagos provides definitions from the Orange Book of two general, therapeutic equivalence ["TE"] codes:

Pharmaceutical Equivalents: drug products which contain the same active ingredients in the same strength and dosage form delivered by the same route of administration; and

Bioequivalent Drug Products: drug products that have shown comparable bioavailability when studied under similar conditions (e.g. the rate and extent of absorption of the test drug does not significantly differ from the reference.

Dr. Panagos explains these TE codes are divided into several sub-codes. She also explains the sub-code "AB rated Drug" indicates: 1) actual or potential bioequivalence problems have been resolved through adequate *in vivo* and/or *in vitro* testing; 2) the generic is interchangeable with the Reference Listed Drug (RLD) brand drug; and, 3) the generic drug mfrs have adequately fulfilled the FDA requirements for the generic's approval. In sum, a TE code of AB rated drug means the generic is identical to the RLD as to its pharmacokinetic and pharmacodynamic properties, mechanism of action,

efficacy, safety, dosage, strength, intended usage, and route of administration.

While her exposition of the Orange Book codes and subcodes is quite useful background, Dr. Panagos, nonetheless, in pages 8-9 of her Report takes that exposition too far. There she opines that an Orange Book TE code on a generic drug expresses a warranty from the generic's manufacturer warranty to TPPs and P&T Committees (agents that aid TPPs in developing drug formularies) that the generic is equivalent to the RLD. As the Court has found for other experts, whether TE codes and subcodes constitute a warranty is a legal question to be posed to, and answered by, the factfinder after a review of relevant facts. Therefore, Dr. Panagos's opinion as to TE codes serving as a mfr's warranty is outside the purview of her expertise.

Inasmuch as Dr. Panagos's Report intertwines methodology (of which there is a measurable scarcity and seems largely based on her years of experience) with opinion, the Court has minutely reviewed her Report. The Court has precluded the opinions in Dr. Panagos's Report at paragraphs 47, 52-59 and in the Summary of Opinions on page 10, paragraphs: B, D, G – I. Her opinions at paragraphs 1 to 46, 49-51 and 54 in her Report and in the Summary of Opinions on page 10, paragraphs: A, C, E, and F have been considered as suitable background.

6.3 PLAINTIFFS' MEDICAL MONITORING EXPERTS

Edward Kaplan, MD

Defendants' motion to Preclude (ECF No. 2024) the Class Certification Report of Edward Kaplan, MD, is **DENIED**. Dr. Kaplan opines on how to develop a screening and monitoring program for plaintiffs exposed to contaminated VCDs. This is fit subject matter for plaintiffs' proposed MedMon classes. As a board-certified oncologist for the last 35 years, a designer of cancer-screening programs for his patients, and a researcher publishing on cancer development and treatment of the following cancers: lymphoma, leukemia, non-small-cell lung, ovarian, breast, leukemia, colorectal, pancreatic, Dr. Kaplan is well qualified to opine on an appropriate medical monitoring program.

Table 10 below shows the medical monitoring program Dr. Kaplan recommends, based on his assumption that all MedMon class members would meet the lifetime cumulative threshold ["LFT"].

Table 10: Summary of Dr. Kaplan's Medical Monitoring Program

Cancer to be Detected	**Testing Tool**	**Frequency** / Cologuard® DNA fecal testing
Pancreatic	Galleri® or similar Liquid Biopsy Testing	Annually
Esophageal/Stomach	Upper Gastrointestinal Endoscopy	Every 5 years
Colon and Rectal	Colonoscopy Additionally, Cologuard® DNA fecal testing	Earlier than 45 years old; If have family history of colon cancer, every 5 years; If no family history of colon cancer, at primary care physician's judgment Annually
Lung	Low Dose CT Chest Scan	Annually
Liver	Blood Tests: CBC; Basic chemistry profile for liver and kidney enzymes; thyroid function; PSA testing (males); Urine analysis	Annually for asymptomatic class members

In her review (ECF 2024-6, Exhibit 5 (D)) of Dr. Kaplan's opinion, defendants' expert Dr. Ursina Teitelbaum agrees with some of Dr. Kaplan's opinions, disagrees with many, and adds testing considerations for other cancers not detailed by Dr. Kaplan. Dr. Teitelbaum's qualifications are appropriate, so is the fit of her opinions as well as her methodology, which is similar to Dr. Kaplan's. Specifically, Dr. Teitelbaum reviews Dr. Kaplan's recommendations for an enhanced medical monitoring protocol for **asymptomatic** individuals who ingested VCDs.

In a nutshell, Dr. Teitelbaum opines that, contrary to Dr. Kaplan's assertions, medical monitoring programs that rely on screening tests are meant only to detect cancers earlier in the progression of the disease and not to mitigate completely the risk of developing cancer. Dr. Teitelbaum also asserts it is unclear whether the asymptomatic medical monitoring class members even have an increased risk of developing cancer, and that the recommended frequency of Dr. Kaplan's screening procedures by itself may actually increase the risk of developing cancer because of the greater exposure to radiation. Dr. Teitelbaum is in effect questioning the need for a medical monitoring program and thereby raising an implied opinion about the increased risk of cancer development, which the Court finds a determination for the factfinder and is therefore not considered.

Dr. Teitelbaum's opinions were unopposed and the Court makes no determination here about their reliability. However, the Court recognizes Dr. Teitelbaum's opinions do not diminish the relevance of Dr. Kaplan's opinions under *FRE 702* and confirms that It has considered Dr. Kaplan's opinions. `

Zirui Song, MD, PhD

Defendants' motion to preclude (ECF No. 2032) the Class Certification Report of plaintiffs' expert, Zirui Song, MD, PhD, is **GRANTED IN PART AND DENIED IN PART**. In ECF No. 2032-3, Dr. Song opines on whether a common methodology can be hypothesized for calculating a health care cost of medical monitoring for each member in the MedMon classes. Considering Dr. Song's teaching and research background, the Court finds him qualified to opine on the economics of health care policy. Nonetheless, in explaining the differences between the expected price of medical monitoring versus its actual cost, Dr. Song's Report theorizes a possible and practical model for estimating the cost of medical monitoring that can be commonly applied to all MedMon class members. However, his theory does not expressly link his opinions to the subject at hand, whether to certify plaintiffs' classes or not. The Court finds that Dr. Song's Report including his proposal on how to calculate a common MedMon Spend has very little actual bearing on the certification requirements of the MedMon class but may have been intended to serve as an ancillary testament to the ascertainability of the *23(b)(3)* IND MedMon class and as an incidental supplement to Dr. Kaplan's Report on the structure of a medical monitoring program.

Using basic economic terms, Dr. Song describes a possible method for calculating the actual medical monitoring costs for the MedMon class. Unfortunately, Dr. Song did not translate his verbal method into an easily understood equation. The Court has done so below:

MEDICAL MONITORING SPEND =		
	Actual cost of MedMon health care service	$\text{Real Cost}_{service}$
TIMES	Number of services, tests, analyses, etc.	S
TIMES	Total Number of members with "Z" insurance coverage, Z = 1 to n,	M_z
TIMES	Number of non-covered services	NCS
DIVIDED BY	Number of covered services.	CS

Dr. Song's model for calculating the Real Cost of medical monitoring translated to:

$$\text{MEDICAL MONITORING SPEND} = \text{Real Cost}_{service} \times S \times M_z \times NCS / CS$$

In their opposition (ECF 2032-1:3), defendants say it succinctly and best: "Dr. Song's 'common methodology' amounts to nothing more than an untested hypothesis that cannot assist the Court in determining whether a medical monitoring class should be certified." Dr. Song's five pages of "methodology", pp. 22 to 26, arises from his insight, thought experiment, and expectations as to how

to calculate the MedMon spend; and there can no doubt he has given serious thought to developing his model, especially because of his expertise. There can also be no doubt the accuracy and effectiveness of his model rests on neither recognized economic literature nor his own or others' research. His model has no tether to a scientifically reliable methodology nor link to class certification requirements.

Notwithstanding that, the majority of his Report elucidates the background of, among other things, how various institutional health care providers on the medical codes for various health service created by the American Medical Association's Current Procedural Terminology Editorial Panel and US Health and Human Services to price out health services. This background, while not specifically relevant to class certification issues, was useful; and for that reason alone, the Court did not preclude the entirety of Dr. Song's Report.

Accordingly, Dr. Song's opinions in pp: 22-26 of his Report on a general method for calculating the spend for medical monitoring services have been precluded but the background information in pp. 8 to 21 in his Report has been considered.

CONCLUSION

Plaintiffs' Motion to certify the Consumer Economic Loss Class is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 3 herein;

Plaintiffs' Motion to certify the Third Party Payor Class is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 4 herein;

Plaintiffs' Motion to certify the *Rule 23(b)(3)* Class of Medical Monitoring as an Independent Claim ["*Rule 23(b)(3)* IND MedMon Class"] is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 7 herein;

Plaintiffs' Motion to certify the *Rule 23(b)(2)* Class of Medical Monitoring as an Independent Claim ["*Rule 23(b)(2)* IND MedMon Class"] is **DENIED without prejudice.** The Court **GRANTS** plaintiffs the option to re-seek class certification of this class by briefing on specific estoppel effects this class may have on the other two certified Medical Monitoring classes; and

Plaintiffs' Motion to certify the *Rule 23(b)(2)* Class of Medical Monitoring as a Remedy is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the corrections in Table 7.

The motions to preclude the opinions in the Class Certification Reports of opposing parties' experts are also decided herein.

Dated: 8 February 2023

s/ Robert B. Kugler
Honorable Robert B. Kugler
United States District Judge

EXHIBIT 2

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

***In re*: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION**	:	Master Docket No. 19-2875 (RBK/SAK)
	:	**Order on Certification of Proposed Classes under FRCP *Rule* 23 and on Class Certification Expert Reports under *FRE* 702**
This Document Applies to All Actions	:	

KUGLER, United States District Judge:

THIS MATTER HAVING COME BEFORE the Court in this multidistrict litigation ("MDL" or "Valsartan MDL") on several motions:

from All plaintiffs: a motion to certify two economic loss classes, each having a number of subclasses, as well as medical monitoring classes; and

from Third Party Payor ["TPP"] plaintiffs: a separate motion to certify a TPP economic loss class; and

from both defendants and plaintiffs seeking to preclude the reports of the class certification experts of the opposing party; and

this Order being accompanied by an Opinion of this date setting forth reasons therein for the rulings below,

IT IS THEREFORE ORDERED, regarding the motions to preclude, or strike, the reports of the parties' class certification experts:

Plaintiffs' Motion to Strike (ECF. No. 2043) New and Altered General Causation Opinions in the Report at ECF No. 2084, Exh. 2 of Michael Bottorff, PharmD is **GRANTED**, and in particular the following opinions of Dr. Bottorff are precluded:

1. "Oral doses at the levels detected in the generic valsartan at issue in this litigation are metabolized in the liver almost completely, **preventing** exposure to other tissues and organs" (Bottorff Class Certification Report at 48:761-762);
2. "NDMA/NDEA in valsartan **will not reach systemic circulation**" (Bottorff Class Certification Report at 47: 779); and
3. "DNA repair mechanisms in humans can be as much as 10 times higher than that in rats,

indicating a more active DNA repair in humans compared to rats" (Bottorff Class Cert. Report at 52:830-831).

Plaintiffs' Motion to Preclude (ECF No. 2038) the Class Certification Report of David Chesney, BA, MSJ, is **GRANTED IN PART AND DENIED IN PART.** Only Mr. Chesney's opinions on page 5 and immediately following in his Class Certification Report and which are limited to the issue of ZHP's compliance with FDA current Good Manufacturing Practices and based solely on his review of ZHP documents have been considered here. The opinions and discussion in the rest of Mr. Chesney's report have been precluded.

Plaintiffs' Motion to Preclude (ECF No. 2047) the Class Certification Report of Jason Clevenger, PhD, is **GRANTED**.

Plaintiffs' Motion to Preclude (ECF No. 2041) the Class Certification Report of Punam Keller, PhD, is **GRANTED IN PART AND DENIED IN PART**. Dr. Keller's opinions on pages 30 to 45 in her Report have been precluded. Her opinions regarding scholarly literature on consumer health decision-making in pages 1-29 of her Report have been considered but only to the extent that these opinions are based on actual consumer surveys and real world consumer research.

Plaintiffs' Motion to Preclude (ECF No. 2048) the Class Certification Report of Timothy Kosty, RPh, MBA, is **GRANTED IN PART AND DENIED IN PART**. The information and opinions in pages 49-99 of Mr. Kosty's Report have been precluded. Mr. Kosty's discussion of the workings of the U.S. pharmaceutical industry in pages 15-48 of his Class Certification Report has been considered.

Plaintiffs' Motion to Preclude (ECF No. 2044) the Class Certification Report of William Lambert, PhD, is **GRANTED IN PART AND DENIED IN PART.** The following opinions in Dr. Lambert's Report have been precluded:

- Dr. Lambert's opinion about the "worthlessness" of the VCDs, couched in terms of bioequivalence, is an unqualified economics opinion,
- Any of Dr. Lambert's opinions that the FDA's Orange Book does or not establish / create manufacturer warranties. By excluding these opinions of Dr. Lambert's, the Court is not expressly deciding one way or another whether the Orange Book creates manufacturer warranties; rather, the Court finds that Dr. Lambert is not a legal expert qualified to opine on such an issue.
- Any of Dr. Lambert's opinions that plaintiffs failed to apply correct standards in determining for bioequivalence and pharmaceutical equivalence.
- Dr. Lambert's opinions at ¶38 of his Class Certification Report; and
- Dr. Lambert's opinions at ¶88 and ¶90 of his Class Certification Report.

Any other of Dr. Lambert's opinions in his Report has been considered.

Plaintiffs' Motion to Preclude (ECF No. 2045) the Class Certification Report of Mark Robbins, PhD, JD is **DENIED.**

Plaintiffs' Motion to Preclude (ECF No. 2036) the Class Certification Report of Eric Sheinin, PhD is **GRANTED IN PART AND DENIED IN PART.** Paragraph 69, and paragraphs 79 to 102 in Dr. Sheinin's Report have been precluded. Paragraphs 25 to 68, and paragraphs 70-78 in Dr. Sheinin's Report have been considered but only as BACKGROUND information, and NOT as reliable expert opinion on class certification, liability, damages, etc. issues.

Plaintiffs' Motion to Preclude (ECF No. 2046) the Class Certification Report of Lauren Stiroh, PhD is **DENIED.**

Defendants' Motions (ECF Nos. 2040 ["General Motion"] and 2037 ['Wholesalers Motion"]) to Preclude the Class Certification Report of Rena Conti, PhD are **DENIED.**

Defendants' Motion to Preclude (ECF No. 2033) the Class Certification Report of Ron Najafi, PhD is **GRANTED.**

Defendants' motion to Preclude (ECF No. 2035) the Class Certification Report of John Quick, MBA, is **GRANTED IN PART AND DENIED IN PART**. Mr. Quick's opinions on pp. 6-7 of his Report regarding the terms "adulterated" and "misbranded" and whether the VCDs were "adulterated" and "misbranded" have been precluded; the other opinions in Mr. Quick's Report have been considered.

Defendants' Motion to Preclude (ECF No. 2034) the Class Certification Report of Kaliopi Panagos, PharmD and RPh, is **GRANTED IN PART AND DENIED IN PART.** Dr. Panagos's opinions at paragraphs 47, and 52-59 in her Report and in the Summary of Opinions on page 10, paragraphs: B, D, G – I have been precluded. Her opinions at paragraphs 1 to 46, 49-51 and 54 in her Report and in the Summary of Opinions on page 10, paragraphs: A, C, E, and F have been considered.

Defendants' Motion to Preclude (ECF No. 2024) the Class Certification Report of Edward Kaplan, MD, is **DENIED**.

Defendants' Motion to preclude the Class Certification Report of Zirui Song, MD, PhD is **GRANTED IN PART AND DENIED IN PART**. Dr. Song's his opinions on a methodology for calculating in a similar way the spend for medical monitoring services in pages 22 through 26 of his Report have been precluded. His discussion of background information in pages 8 through 21 in his Report has been considered.

IT IS FURTHER ORDERED, regarding plaintiffs' motions to certify certain classes:

Plaintiffs' Motion to certify the Consumer Economic Loss Class is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 3 herein;

Plaintiffs' Motion to certify the Third Party Payor Class is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 4 herein;

Plaintiffs' Motion to certify the *Rule 23(b)(3)* Class of Medical Monitoring as an Independent Claim ["*Rule 23(b)(3)* IND MedMon Class"] is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 7 herein;

Plaintiffs' Motion to certify the *Rule 23(b)(2)* Class of Medical Monitoring as an Independent Claim ["*Rule 23(b)(2)* IND MedMon Class"] is **DENIED without prejudice.** The Court **GRANTS** plaintiffs the option to re-seek class certification of this class by briefing on the specific estoppel effects this class may have on the other two certified Medical Monitoring classes;

Plaintiffs' Motion to certify the *Rule 23(b)(2)* Class of Medical Monitoring as a Remedy is **GRANTED BUT REQUIRES** plaintiffs to amend their proposed subclasses in line with the recommendations in Table 7 herein; and

IT IS FURTHER ORDERED:

Defendants' Motion (ECF No. 2069) for leave to file instanter sur-reply briefs in further opposition to plaintiffs motions for class certification, and Request for a class certification hearing is **DENIED** as made moot by this Opinion.

Dated: 8 February 2023

s/ Robert B. Kugler
Honorable Robert B. Kugler
United States District Judge

In re: IN RE: VALSARTAN LOSARTAN AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.;
HUAHAI U.S. INC; PRINSTON PHARMACEUTICAL INC; SOLCO HEALTHCARE US LLC;
TEVA PHARMACEUTICALS USA INC; TEVA PHARMACEUTICAL INDUSTRIES LTD; ACTAVIS LLC;
HETERO USA INC; CAMBER PHARMACEUTICALS INC; HETERO DRUGS LTD;
HETERO LABS LTD; TORRENT PHARMACEUTICALS LTD; TORRENT PHARMA INC.,

Petitioner

PATRICIA S. DODSZUWEIT

CLERK

OFFICE OF THE CLERK

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February 24, 2023

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RE: In Re: Valsartan Losartan and Irbesartan Products, et al, et al
Case Number: 23-8005
District Court Case Number: 1-19-md-02875

PACER account holders are required to promptly inform the PACER Service Center of any contact information changes. In order to not delay providing notice to attorneys or pro se public filers, your information, including address, phone number and/or email address, may have been updated in the Third Circuit database. Changes at the local level will not be reflected at PACER. Public filers are encouraged to review their information on file with PACER and update if necessary.

To All Parties:

The Clerk has received a petition for leave to appeal filed by **Hetero USA Inc, Actavis LLC, Torrent Pharma Inc, Hetero Drugs Ltd, Huahai U.S. Inc, Camber Pharmaceuticals Inc, Teva Pharmaceuticals USA Inc, Torrent Pharmaceuticals Ltd, Prinston Pharmaceutical Inc, Solco Healthcare US LLC, Teva Pharmaceutical Industries Ltd, Hetero Labs Ltd, Zhejiang Huahai Pharmaceutical Co., Ltd.**, docketed at **No. 23-8005**. All inquiries should be directed to your Case Manager in writing or by calling the Clerk's Office at 215-597-2995. This Court's rules, forms, and case information are available on our website at http://www.ca3.uscourts.gov.

Counsel for Petitioner
As counsel for Petitioner(s), you must file:
1. Application for Admission (if applicable);
2. Appearance Form; and,
3. Disclosure Statement (except governmental entities), if not included in petition.
These forms must be filed within **fourteen (14) days of the date of this letter**.

Should the Court grant the petition for leave to appeal, additional forms and the appellate portion of the filing and docketing fee will be required.

Any response in opposition must be filed **within ten (10) days** of the date of this letter. **All responses must be accompanied by an Appearance Form and Disclosure Statement.** The

petition and any response(s) will be forwarded to the Court for disposition. The parties will be advised when an order is entered by the Court.

Parties who do not intend to participate in the petition must notify the Court in writing.

Very truly yours,
Patricia S. Dodszuweit, Clerk

By: Pamela Batts
Pamela Batts, Case Manager
267-299-4943

cc:

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Rachel German, Esq.
Gregory P. Hansel, Esq.
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